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Wednesday
September 16, 1998

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Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Proclamation 7120 of September 12, 1998

Ovarian Cancer Awareness Week, 1998

By the President of the United States of America

A Proclamation

We have many weapons at hand in our war against cancer, and among the most effective is early diagnosis. With ovarian cancer in particular—sometimes called the ''silent killer'' because it shows no obvious signs or symptoms until late in its development—early diagnosis can mean the difference between life and death. Of the estimated 26,000 American women who were diagnosed with ovarian cancer last year, an estimated 14,000 died. Currently, almost 70 percent of women with ovarian cancer are not diagnosed until the disease is in its advanced stages; in many cases, the cancer has already spread by the time it is discovered.

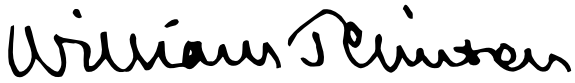
We know relatively little about why some women develop this deadly disease. While every woman is at risk, we do know that ovarian cancer occurs somewhat more frequently in women who have never been pregnant. Women who have had breast cancer or who have a family history of breast or ovarian cancer are also at increased risk. There are other genetic factors as well that can affect the incidence of ovarian cancer.

We do have hope in our fight against this cancer. Scientists at medical centers and hospitals across our Nation are developing significant new information that holds promise for the future, particularly for research in genetic susceptibility and prevention, diagnostic imaging, screening and diagnosis, and treatment. For example, because of their knowledge about the ovarian cancer risk genes, researchers are now able to work on developing prevention and screening with women in families at high risk. Researchers are also making progress in the area of treatment through improvements in existing chemotherapy regimens.

While we take heart from these promising developments, we also recognize the need for an increased awareness and understanding of ovarian cancer. As we observe Ovarian Cancer Awareness Week and affirm our national commitment to fighting this devastating disease, I encourage all American women and their families to learn more about ovarian cancer, and I urge health care professionals to emphasize to their patients the importance of regular examinations. By doing so, we can build on the progress we have made in our crusade against cancer and ensure healthier, longer lives for women.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim September 13 through September 19, 1998, as Ovarian Cancer Awareness Week. I encourage the American people to observe this week with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of September, in the year of our Lord nineteen hundred and ninety-eight, and of the Independence of the United States of America the two hundred and twenty-third.



[FR Doc. 98–24945
Filed 9–15–98; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

RIN 3150–AG00

Physical Protection for Spent Nuclear Fuel and High-Level Radioactive Waste: Technical Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations concerning the physical protection of spent nuclear fuel and high-level radioactive waste stored at independent spent fuel storage installations, monitored-retrievable storage installations, and geologic repository operations areas. This action is necessary to correct the inappropriate inclusion of surveillance/assessment and illumination systems within the requirement for tamper indication and line supervision.

DATES: The final rule is effective November 12, 1998, unless significant adverse comment is received by October 16, 1998. If the rule is withdrawn, timely notice will be published in the **Federal Register**.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). From the home page, select ''Rulemaking'' from the tool bar. The interactive rulemaking website can then be accessed by selecting ''New Rulemaking Website.'' This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905, e-mail cag@nrc.gov.

Copies of any comments received may be examined at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Barry Mendelsohn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7262.

SUPPLEMENTARY INFORMATION: Because NRC considers this action noncontroversial, the NRC is publishing it in final form. This action will become effective on November 12, 1998. However, if the NRC receives significant adverse comment by October 16, 1998, the NRC will publish a document that withdraws this action. In the proposed rules section of this issue of the **Federal Register**, NRC is publishing a separate document that will serve as the proposal to approve the rule should adverse comment be received. Any significant adverse comment will be addressed in a subsequent final rule. The NRC will not initiate a second comment period on this action.

Background

The purpose of this amendment to 10 CFR 73.51, ''Physical Protection for Spent Fuel and High-Level Radioactive Waste'' and, specifically, paragraph (d)(11), is to delete surveillance/assessment and illumination systems from the requirement for tamper indication and line supervision. These types of systems were added to this particular portion of the regulation in error and it is not the intent of the NRC that affected licensees provide tamper indication or line supervision for required surveillance/assessment and illumination systems. This protection is not needed because these systems are considered ''self-protecting,'' i.e., tampering produces an obvious loss of function rather than an unobvious degradation. The requirement for surveillance/assessment and illumination systems to be maintained in operable condition remains unchanged. This rulemaking also supersedes guidance found in the Statement of Consideration of the **Federal Register** Notice for the Physical Protection for Spent Fuel and High-Level Radioactive Waste (May 15,1998, 63 FR 26955). On page 26960, under the section-by-section comparison of the proposed versus final rule, the discussion regarding proposed section 73.51(d)(13), revised as section (d)(11), is amended to be consistent with the corrective text of this rulemaking.

Environmental Impact: Categorical Exclusion

The Commission has determined that this final rule is the type of action descibed in categorical exclusion 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval number 3150–0002.

Public Protection Notification

If an information collection does not display a currently valid OMB number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

A regulatory analysis has not been prepared for this Direct Final Rule because this rule is corrective in nature and is considered a minor, nonsubstantive amendment; it has no economic impact on NRC licensees or the public.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1989, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant impact upon a substantial number of small entities. The regulation affects entities licensed to operate independent spent fuel storage installations, monitored-retrievable storage installations, and geologic repository operations areas. These entities do not fall within the definition of small entities.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this rule and, therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 73

Criminal penalties, Hazardous materials transportaion, Exports, Imports, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following final amendment to 10 CFR Part 73.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C, 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99–399, 100 Stat. 876 (42 U.S.C. 2169).

2. Section 73.51(d)(11) is revised to read as follows:

§ 73.51 Requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste.

* * * * *

(d) * * *

(11) All detection systems and supporting subsystems must be tamper indicating with line supervision. These systems, as well as surveillance/assessment and illumination systems, must be maintained in operable condition. Timely compensatory measures must be taken after discovery of inoperability, to assure that the effectiveness of the of the security system is not reduced.

* * * * *

Dated at Rockville, Maryland, this 26th day of August, 1998.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 98–24715 Filed 9–15–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–31–AD; Amendment 39–10736; AD 98–18–20]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727 and Model 737 Series Airplanes Equipped with J.C. Carter Company Fuel Valve Actuators

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 727 and Model 737 series airplanes, that requires replacement of the actuator of the engine fuel shutoff valve and the fuel system crossfeed valve with an improved actuator. This amendment is prompted by a report indicating that, during laboratory tests, the actuator clutch on the engine fuel shutoff and crossfeed valves failed to function properly. The actions specified by this AD are intended to prevent improper functioning of these actuators, which could result in a fuel imbalance due to the inability of the flightcrew to crossfeed fuel; improperly functioning actuators also could prevent the pilot from shutting off the fuel to the engine following an engine failure and/or fire.

DATES: Effective October 21, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 21, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from J.C. Carter Company Inc., Aerospace Components and Repair Service, 673 W. 17th Street, Costa Mesa, California 92627–3605. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sulmo Mariano, Aerospace Engineer; Propulsion Branch, ANM–140S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2175; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 727 and 737 series airplanes was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on March 26, 1997 (62 FR 14373). That action proposed to require replacement of the actuator of the engine fuel shutoff valve and the fuel system crossfeed valve with an improved actuator. That action also proposed to expand the applicability of the proposed rule by including an additional Kearfott actuator that is subject to the addressed unsafe condition.

Explanation of New Service Information

The FAA has reviewed and approved J.C. Carter Company Service Bulletin 61163–28–09, dated May 1, 1996. Although no service bulletin revision level was designated, this new service bulletin was issued as an updated revision of the original version, dated September 28, 1995, which was referenced in the supplemental NPRM as the appropriate source of service information for accomplishment of the proposed replacement. The procedures described in these two service bulletins are essentially the same. However, the new revision includes the following additional clarifying information:

1. In Section II, Accomplishment Instructions, an additional reference to 737 Maintenance Manual (MM) 28–22–11/400 was added to the first paragraph.

2. In Section III, Materials, only two relevant changes were made. First, a new optional actuator part number, 40574–1, was added to the itemized list of part numbers. Second, information regarding the model number and nameplate of the new actuator was added to the second Note following the list of part numbers. In addition, information regarding the nameplates for Kearfott actuator models 3715–7 and 3715–8 was added to the first two headings following the Note paragraphs.

Comments Received

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Several commenters support the proposed rule. However, two other commenters suggest certain changes to the supplemental NPRM, which are discussed in the following paragraphs.

Request to Stop Issuance

One commenter suggests that issuance of a new AD is unnecessary for two reasons:

1. The commenter states that, ''based upon the number of parts not returned to J.C. Carter to date, it appears that these parts are meeting their life requirement of 10,000 cycles.'' The commenter also states that, ''since the clutch binding problem results in a hard failure with indication, we believe that the potential clutch binding is not a safety issue and thus, an AD is not necessary for part numbers 3715–8 and 3715–9.''

The FAA does not concur with the commenter's statements. The FAA has determined that the fundamental issue is the improper functioning of certain actuators due to clutch binding, which could result in a fuel imbalance due to the inability of the flightcrew to crossfeed fuel or prevent the pilot from shutting off the fuel to the engine following an engine failure or fire. The FAA has determined that clutch binding is an identified safety issue, that an airworthiness directive is the appropriate vehicle for mandating such action to correct the unsafe condition, and that issuance of the final rule to identify such part numbers is appropriate and necessary to ensure the continued safety of the fleet.

2. This same commenter advises that part number (P/N) 3715–7 actuators had a brush-sticking problem at cold temperatures and that this problem is latent. The commenter also advises that all but 16 of such actuators have been removed from service and returned to J.C. Carter, the discrepant parts are being tracked, the locations of 14 of the 16 discrepant parts are known, and the locations of the remaining discrepant parts are being pursued for their removal from service. The commenter states that it will continue to pursue removal of P/N 3715–7 actuators from service regardless of whether an airworthiness directive is issued.

The FAA acknowledges that the manufacturer is continuing its efforts to remove all of the discrepant P/N 3715–7 actuators from service. However, in accordance with various bilateral airworthiness agreements with countries around the world, the FAA is obligated to advise foreign airworthiness authorities of unsafe conditions identified in products manufactured in the United States; the issuance of AD's is the means by which the FAA satisfies this obligation. Therefore, the issuance of this AD is both warranted and necessary.

Request to Reduce Number of Affected Airplanes

The airplane manufacturer states that J.C. Carter estimates there are only 200 Kearfott actuators that may be in service. The commenter adds that, therefore, the number of airplanes that will require accomplishment of the AD is much lower than the 2,190 airplanes estimated in the supplemental NPRM. The FAA acknowledges that 200 actuators may be in service. However, because these actuators could be installed on any airplane in the fleet of 2,190 U.S.-registered airplanes, the FAA finds it appropriate to reflect that number in the cost impact information, below. No change to the final rule is necessary in this regard.

Request to Cite Latest Service Bulletin Revision

One commenter states that the updated revision of J.C. Carter Service Bulletin 61163–28–09, dated May 1, 1996, is approved by the FAA and has been released to all operators. Because this service bulletin includes the new optional actuator part number and some additional information, the commenter requests that the action required by the supplemental NPRM be accomplished in accordance with the latest service bulletin. Another commenter states that, ''The release date of J.C. Carter Service Bulletin 61163–28–09 is May 1, 1996, not September 28, 1995.''

The FAA concurs with the requests to cite the latest release of this service bulletin (described previously). The FAA has determined that the new optional actuator part does not impose any additional burden or cost on the operator. Paragraph (a) of the final rule has been changed to cite both versions of the service bulletin as appropriate sources of service information for accomplishment of the replacement.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 4,137 Model 727 and 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 2,190 airplanes of U.S. registry will be affected by this AD, that it will take approximately 3 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts would be supplied by J.C. Carter Company at no cost to operators. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $394,200, or $180 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the

Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–18–20 Boeing: Amendment 39–10736. Docket 96–NM–31–AD.

Applicability: Model 727 and Model 737 series airplanes, equipped with J.C. Carter Company fuel valve actuators having part number (P/N) 40574–2 (Kearfott Models 3715–7 and –8) or 40574–5 (Kearfott Model 3715–9); certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent improper functioning of a certain actuator, which could result in a fuel imbalance due to the inability of the flightcrew to crossfeed fuel, or which could prevent the pilot from shutting off the fuel to the engine following an engine failure and/or fire, accomplish the following:

(a) Within 36 months after the effective date of this AD, replace any actuator having P/N 40574–2 (Kearfott Models 3715–7 and –8) or P/N 40574–5 (Kearfott Model 3715–9) on the fuel system crossfeed valve and the engine shutoff valves with either a new actuator having P/N 40574–1 (General Design Model 3715–6) or P/N 40574–4, or an actuator having P/N 40574–2 with a nameplate identified in paragraph III, Material, of either J.C. Carter Company Service Bulletin 61163–28–09, dated September 28, 1995, or J.C. Carter Company Service Bulletin, 61163–28–09, dated May 1, 1996, that is not affected by a manufacturer's recall (reference Figure 1.0 of the service bulletin). The replacement shall be done in accordance with either J.C. Carter Company Service Bulletin 61163–28–09, dated September 28, 1995, or J.C. Carter Company Service Bulletin 61163–28–09, dated May 1, 1996.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The replacement shall be done in accordance with either J.C. Carter Company Service Bulletin 61163–28–09, dated September 28, 1995, or J.C. Carter Company Service Bulletin 61163–28–09, dated May 1, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from J.C. Carter Company Inc., Aerospace Components and Repair Service, 673 W. 17th Street, Costa Mesa, California 92627–3605. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on October 21, 1998.

Issued in Renton, Washington, on August 28, 1998.

Vi L. Lipski,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24245 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–10–AD; Amendment 39–10754; AD 98–19–12]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce, plc RB211 Trent 700 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Rolls-Royce, plc RB211 Trent 700 series turbofan engines. This action requires repositioning of the oil metering jet up into the oil distributor within the bevel gearshaft, followed by repetitive inspections of the Magnetic Chip Detector (MCD). Evidence of driving bevel gearshaft ball bearing failure requires replacement of the Step Aside Gearbox (SAGB). This amendment is prompted by reports of uncommanded engine rundowns caused by failure of the SAGB driving bevel gearshaft ball bearing due to oil starvation. This causes a loss of drive to the external gearbox and accessories, resulting in an inflight engine shutdown. The actions specified in this AD are intended to prevent inflight engine shutdowns caused by SAGB driving bevel gearshaft ball bearing failure.

DATES: Effective October 1, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 1, 1998.

Comments for inclusion in the Rules Docket must be received on or before November 16, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–ANE–10–AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may also be sent via the Internet using the following address: ''9-ad-engineprop@faa.dot.gov''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from Rolls-Royce North America, Inc., 2001 South Tibbs Ave., Indianapolis, IN 46241; telephone (317) 230-3995, fax (317) 230–4743. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7176, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom (UK), recently notified the FAA that an unsafe condition may exist on Rolls-Royce, plc (R–R) RB211 Trent 700 series turbofan engines. The CAA advises that they have received reports of 4 uncommanded engine rundowns caused by failure of the Step Aside Gearbox (SAGB) driving bevel gearshaft ball bearing and loss of drive to the external gearbox and accessories, resulting in an inflight shutdown. The

investigation revealed that the ball bearing failures were due to inadequate oil flow to the bearing as a result of movement of the oil jet due to windage affects inside the gearbox. There are currently no affected engines operated on aircraft of U.S. registry. This AD, then, is necessary to require accomplishment of the required actions for engines installed on aircraft currently of foreign registry that may someday be imported into the U.S. Accordingly, the FAA has determined that notice and prior opportunity for comment are unnecessary and good cause exists for making this amendment effective in less than 30 days. This condition, if not corrected, could result in inflight engine shutdowns caused by SAGB driving bevel gearshaft ball bearing failure.

R-R has issued Service Bulletin (SB) No. RB.211–72–C270, dated June 1, 1997, that specifies procedures for repositioning the oil metering jet up into the oil distributor within the bevel gearshaft, and SB No. RB.211–79–C135, dated July 4, 1997, that specifies procedures for inspections of the Magnetic Chip Detector for evidence of SAGB driving bevel gearshaft ball bearing failure. The CAA classified these SBs as mandatory and issued ADs 001–05–97 and 002–06–97 in order to assure the airworthiness of these engines in the UK.

This engine model is manufactured in the UK and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other engines of the same type design registered in the United States, this AD requires, prior to further flight, repositioning of the oil metering jet up into the oil distributor within the bevel gearshaft. In addition, this AD requires repetitive inspections of the Magnetic Chip Detector at intervals between 60 hours minimum time in service (TIS) and 130 hours maximum TIS since last inspection. If evidence of a bearing failure is found, this AD requires replacement of the Step Aside Gearbox with a serviceable part. The actions would be required to be accomplished in accordance with the SBs described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–ANE–10–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–19–12 Rolls-Royce, plc: Amendment 39–10754. Docket 98–ANE–10–AD.

Applicability: Rolls-Royce, plc (R–R) RB211 Trent 700 series turbofan engines, installed on but not limited to Airbus A330 series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent inflight engine shutdowns caused by Step Aside Gearbox (SAGB) driving bevel gearshaft ball bearing failure, accomplish the following:

(a) Prior to further flight, reposition the oil metering jet up into the oil distributor within the bevel gearshaft in accordance with R–R Service Bulletin (SB) No. RB.211–72–C270, dated June 1, 1997.

(b) Perform initial and repetitive inspections of the Magnetic Chip Detector for evidence of SAGB driving bevel gearshaft ball bearing failure in accordance with R–R SB No. RB.211–79–C135, dated July 4, 1997, as follows:

(1) Perform the initial inspection in accordance with R–R SB No. RB.211–79–C135, within 60 hours time in service (TIS) after repositioning the oil metering jet up into the oil distributor within the bevel gearshaft in accordance with R–R Service Bulletin (SB) No. RB.211–72–C270.

(2) Thereafter, inspect at intervals between 60 hours minimum TIS and 130 hours maximum TIS since last inspection.

(3) If evidence of a SAGB driving bevel gearshaft ball bearing failure is found, replace the SAGB with a serviceable part.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(d) Special flight permits may be issued in accordance with §§ sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the inspection requirements of this AD can be accomplished.

(e) The actions required by this AD shall be performed in accordance with the following R–R SBs:

Document No.	Pages	Date
RB.211–72–C270 Total pages: 7.	1–7	June 1, 1997.
RB.211–79–C135 Total pages: 2.	1–2	July 4, 1997.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Rolls-Royce North America, Inc., 2001 South Tibbs Ave., Indianapolis, IN 46241; telephone (317) 230–3995, fax (317) 230–4743. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on October 1, 1998.

Issued in Burlington, Massachusetts, on September 8, 1998.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 98–24645 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–07–AD; Amendment 39–10753; AD 98–19–11]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Limited, Aero Division-Bristol/ S.N.E.C.M.A. Olympus 593 Series Turbojet Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Rolls-Royce Limited, Aero Division-Bristol/S.N.E.C.M.A. Olympus 593 series turbojet engines. This action requires initial and repetitive X-ray and ultrasonic inspections of exhaust diffuser vanes for corrosion and cracks, and, if necessary, removal from service of cracked exhaust diffusers and replacement with serviceable parts. This amendment is prompted by reports of 17 turbine exhaust diffuser modules with one or more exhaust diffuser vanes cracked. The actions specified in this AD are intended to prevent exhaust diffuser vane failure, which could result in an adverse effect on the engine oil and reheat systems, possibly causing an inflight engine shutdown or damage to the aircraft.

DATES: Effective October 1, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 1, 1998.

Comments for inclusion in the Rules Docket must be received on or before November 16, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–ANE–07–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ad-engineprop@faa.dot.gov''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from Rolls-Royce, PO Box 3, Filton, Bristol BS12 7QE, England; telephone 01–17–979–1234, fax 01–17–979–7575. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7747, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom (UK), recently notified the Federal Aviation Administration (FAA) that an unsafe condition may exist on Rolls-Royce Limited, (R–R)Aero Division-Bristol/S.N.E.C.M.A. Olympus 593 Mk. 610–14–28 turbojet engines. The CAA advises that they have received reports of 17 turbine exhaust diffuser modules containing at least one cracked exhaust diffuser vane. In some cases the exhaust diffuser vanes peeled back due to vane leading edge cracking. If the exhaust diffuser vanes peel back, they can possibly expose the engine oil and reheat systems imbedded inside the exhaust diffuser vane and result in bearing sump damage. There are currently no affected engines operated on aircraft of U.S. registry. This AD, then, is necessary to require accomplishment of the required actions for engines installed on aircraft currently of foreign registry that may someday be imported into the U.S. Accordingly, the FAA has determined that notice and prior opportunity for comment are unnecessary and good cause exists for making this amendment effective in less than 30 days. This condition, if not corrected, could result in exhaust diffuser vane failure, which could result in an adverse effect on the engine oil and reheat systems, possibly causing an inflight engine shutdown or damage to the aircraft.

R–R has issued Service Bulletin (SB) No. OL.593–72–9042–422, Revision 1, dated May 23, 1997, that specifies procedures for X-ray inspections of exhaust diffuser vanes for cracks and corrosion, and if found cracked, removal from service of the exhaust diffuser and

replacement with a serviceable part. In addition, R–R has issued SB No. OL.593–72–9047–423, dated January 31, 1997, that specifies procedures for ultrasonic inspections of corroded exhaust diffuser vanes for leading edge cracks, and if the exhaust diffuser fails inspection, removal from service of the exhaust diffuser and replacement with a serviceable part. The CAA classified these SBs as mandatory and issued ADs 005–01–97 and 006–01–97 in order to assure the airworthiness of these engines in the UK.

This engine model is manufactured in the UK and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other engines of the same type design registered in the United States, the AD requires initial and repetitive X-ray and ultrasonic inspections of exhaust diffuser vanes for cracks and corrosion, and, if necessary, removal from service of the exhaust diffuser and replacement with a serviceable part. The actions would be required to be accomplished in accordance with the SBs described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–ANE–07–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–19–11 Rolls-Royce Limited, Aero Division-Bristol/S.N.E.C.M.A.: Amendment 39–10753. Docket 98–ANE–07–AD.

Applicability: Rolls-Royce Limited, (R–R) Aero Division-Bristol/S.N.E.C.M.A. Olympus 593 Mk. 610–14–28 turbojet engines, installed on but not limited to British Aerospace/Aerospatiale Concorde series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent an exhaust diffuser vane failure, which could result in an adverse effect on the engine oil and reheat systems, possibly causing an inflight engine shutdown or damage to the aircraft, accomplish the following:

(a) Perform initial and repetitive X-ray inspections of exhaust diffuser vanes for cracks and corrosion, in accordance with R–R/S.N.E.C.M.A. Service Bulletin (SB) No. OL.593–72–9042–422, Revision 1, dated May 23, 1997, as follows:

(1) Perform the initial inspection at the first module exposure after accumulating 5,000 hours time since new (TSN).

(2) Thereafter, perform inspections at every module exposure, or 2,000 hours time in service (TIS) since last X-ray inspection, whichever occurs later.

(3) If an exhaust diffuser vane is found cracked, remove the exhaust diffuser from service and replace with a serviceable part.

(4) If any evidence of corrosion is found, perform an ultrasonic inspection for cracks in accordance with paragraph (b) of this AD.

(b) Perform initial and repetitive ultrasonic inspections for corrosion in the exhaust diffuser vanes in accordance with R–R/

S.N.E.C.M.A. SB No. OL.593–72–9047–423, dated January 31, 1997, as follows:

(1) Perform the initial inspection no later than 1,000 hours TIS since last X-ray inspection in accordance with paragraph (a) of this AD if no cracks are detected but corrosion is found.

(2) Thereafter, perform inspections at intervals not to exceed 250 hours TIS since last ultrasonic inspection, or 1,000 hours TIS since an X-ray inspection that discovered no cracks, whichever occurs later.

(3) If cracking is found, remove the exhaust diffuser from service and replace with a serviceable part.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the inspection requirements of this AD can be accomplished.

(e) The actions required by this AD shall be performed in accordance with the following R–R SBs:

Document No.	Pages revision	Date
OL.593–72–9042–422. Total pages: 5	1–5 1	May 23, 1997.
OL.593–72–9047–423. Total pages: 7	1–7 Original	January 31, 1997.

This incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Rolls-Royce, P.O. Box 3, Filton, Bristol BS12 7QE, England; telephone 01–17–979–1234, fax 01–17–979–7575. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the **Federal Register**, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on October 1, 1998.

Issued in Burlington, Massachusetts, on September 8, 1998.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 98–24643 Filed 9–16–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–42–AD; Amendment 39–10760; AD 98–19–19]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB 2000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Saab Model SAAB 2000 series airplanes, that requires a one-time inspection to detect discrepancies of the electrical harness of the propeller de-icing system and of the hydraulic pressure pipe from the engine driven pump (EDP); and follow-on corrective actions, if necessary. This action is prompted by the issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent chafing of the hydraulic pressure pipe of the EDP, which could result in charring of the hydraulic tube and consequent engine compartment fire.

DATES: Effective October 21, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 21, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linkping, Sweden. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Saab Model SAAB 2000 series airplanes was published in the **Federal Register** on March 26, 1998 (63 FR 14651). That action proposed to require a one-time inspection to detect discrepancies of the electrical harness of the propeller de-icing system and of the hydraulic pressure pipe from the engine driven pump (EDP); and follow-on corrective actions, if necessary.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposed rule.

One commenter requests that the FAA change paragraph (a)(1) of the proposed rule from ''prior to further flight, repair in accordance with the service bulletin,'' to ''prior to further flight, if the routing is not correct, it must be rerouted in accordance with Saab Service Bulletin SAAB 2000–30–14 (the appropriate service information referenced in the proposed rule); that a minimum clearance between the pipe and harness has to be assured; and that, if there is chafing through the outer jacket or into the wires, the electrical harness should be repaired.'' The commenter provided no justification for the suggested change to the proposed rule.

The FAA concurs that the actions to correct any discrepancies could be more specific. Therefore, the FAA has revised paragraph (a)(1) of the final rule to further define and clarify specific ''repair'' actions as the commenter requests, and as specified in the service bulletin.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change described previously. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 3 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $180, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD

action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–19–19 SAAB AIRCRAFT AB: Amendment 39–10760. Docket 98–NM–42–AD.

Applicability: Saab Model SAAB 2000 series airplanes, serial numbers 004 through 053 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent chafing of the hydraulic pressure pipe of the engine driven pump (EDP), which could result in charring of the hydraulic tube and consequent engine compartment fire, accomplish the following:

(a) Within 30 days after the effective date of this AD, accomplish the actions specified in paragraphs (a)(1) and (a)(2) of this AD, in accordance with Saab Service Bulletin SAAB 2000–30–014, Revision 01, dated January 9, 1998.

(1) Perform a one-time inspection to detect discrepancies (incorrect routing, insufficient clearance, and chafing) of the electrical harness of the propeller de-icing system, left and right sides. If any discrepancy is found, prior to further flight, repair in accordance with the service bulletin. Repair of any discrepancy may involve, but is not limited to, the following corrective actions: Rerouting wires, ensuring adequate clearance between the pipe and the harness, and repairing the electrical harness if chafing has occurred through the outer jacket or into the wires.

(2) Perform a one-time visual inspection to detect chafing of the hydraulic pipe of the EDP, left and right sides. If any chafing is found, prior to further flight, replace the pipe with a new or serviceable part.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The actions shall be done in accordance with Saab Service Bulletin SAAB 2000–30–014, Revision 01, dated January 9, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linköping, Sweden. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Swedish airworthiness directive SAD No. 1–121, dated January 9, 1998.

(e) This amendment becomes effective on October 21, 1998.

Issued in Renton, Washington, on September 9, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24658 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–107–AD; Amendment 39–10759; AD 98–19–18]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310, A300–600, and A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Airbus Model A310, A300–600, and A320 series airplanes, that currently requires inspections to verify proper installation of the grill over the air extraction duct of the lavatory and to detect blockages in the air extraction duct of the lavatory, and correction of any discrepancies. This amendment adds a requirement for modification of the grill of the air extraction duct, which, when accomplished, terminates the repetitive inspections. This amendment also expands the applicability of the existing AD to include additional airplanes. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent obstructions in the air extraction system of the lavatory, which may result in the failure of the smoke detection system to detect smoke in the lavatories.

DATES: Effective October 21, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 21, 1998.

The incorporation by reference of Airbus AOT 26–12, Revision 1, dated

July 4, 1994, was approved previously by the Director of the Federal Register as of March 17, 1995 (60 FR 11619, March 2, 1995).

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 95–04–12, amendment 39–9164 (60 FR 11619, March 2, 1995), which is applicable to certain Airbus Model A310, A300–600, and A320 series airplanes, was published in the **Federal Register** on July 24, 1998 (63 FR 39771). The action proposed to continue to require inspections to verify proper installation of the grill over the air extraction duct of the lavatory and to detect blockages in the air extraction duct of the lavatory, and correction of any discrepancies. The action also proposed to add a requirement for modification of the grill of the air extraction duct, which, when accomplished, would terminate the repetitive inspections. The action also proposed to expand the applicability of the existing AD to include additional airplanes.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the two comments received.

One commenter supports the proposed rule; the other commenter has no objection to the proposed rule.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

There are approximately 36 Airbus Model A310 series airplanes, 54 Airbus Model A300–600 series airplanes, and 118 Airbus Model A320 series airplanes of U.S. registry that will be affected by this AD.

The inspections that are currently required by AD 95–04–12, and retained in this AD, take approximately 2 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required inspections on U.S. operators is estimated to be $24,960, or $120 per airplane, per inspection cycle.

For Airbus Model A310 series airplanes, the new required modification will take approximately 5 work hours per airplane (5 lavatories per airplane; 1 work hour per lavatory) to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the modification required by this AD on U.S. operators of Airbus Model A310 series airplanes is estimated to be $10,800, or $300 per airplane.

For Airbus Model A300–600 and A320 series airplanes, the new required modification will take approximately 10 work hours per airplane (5 lavatories per airplane; 2 work hours per lavatory) to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the modification required by this AD on U.S. operators of Airbus Model A300–600 and A320 series airplanes is estimated to be $103,200, or $600 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9164 (60 FR 11619, March 2, 1995), and by adding a new airworthiness directive (AD), amendment 39–10759, to read as follows:

98–19–18 AIRBUS INDUSTRIE: Docket 97-NM–107-AD. Supersedes AD 95–04–12, Amendment 39–9164.

Applicability: Model A310 and A300–600 series airplanes on which Airbus Modification 10156 has not been accomplished (reference Airbus Service Bulletin A310–26–2023 or A300–26–6024), and Model A320 series airplanes on which Airbus Modification 22561 (reference Airbus Service Bulletin A320–26–1017) or Airbus Modification 24548 (reference Airbus Service Bulletin A320–26–1037) has not been accomplished; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent obstructions in the air extraction system of the lavatory, which may result in the failure of the smoke detection

system to detect smoke in the lavatories, accomplish the following:

Restatement of Requirements of AD 95–04–12

(a) Within 450 flight hours after March 17, 1995 (the effective date of AD 95–04–12), perform an inspection of each lavatory to verify proper installation of the grill over the air extraction duct of the lavatories, and to detect blockage in the air extraction duct of the lavatories, in accordance with Airbus All Operators Telex (AOT)
26–12, Revision 1, dated July 4, 1994.

(1) If the grill is found to be properly installed and if no blockage is found, repeat the inspection thereafter whenever the cover over the air extraction duct of the lavatories or any ceiling louver (grill) of the ceiling light in the lavatory is removed or replaced for any reason.

(2) If the grill is found to be improperly installed and/or if blockage is found, prior to further flight, correct any discrepancies found, in accordance with Airbus AOT 26–12, Revision 1, dated July 4, 1994. Repeat the inspection thereafter whenever the cover over the air extraction duct of the lavatories or any ceiling louver (grill) of the ceiling light in the lavatory is removed or replaced for any reason.

New Requirements of This AD

(b) Within 500 flight hours after the effective date of this AD, modify the grill of the air extraction duct of the lavatory, in accordance with Airbus Service Bulletin A310–26–2030, Revision 02, dated April 4, 1997 (for Model A310 series airplanes); A300–26–6030, Revision 02, dated April 4, 1997 (for Model A300–600 series airplanes); or A320–26–1037, Revision 02, dated July 8, 1997 (for Model A320 series airplanes); as applicable. Accomplishment of the modification constitutes terminating action for the inspection requirements of paragraph (a) of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The actions shall be done in accordance with Airbus AOT 26–12, Revision 1, dated July 4, 1994; Airbus Service Bulletin A310–26–2030, Revision 02, dated April 4, 1997; Airbus Service Bulletin A300–26–6030, Revision 02, dated April 4, 1997; or Airbus Service Bulletin A320–26–1037, Revision 02, dated July 8, 1997; as applicable.

(1) The incorporation by reference of Airbus Service Bulletin A310–26–2030, Revision 02, dated April 4, 1997; Airbus Service Bulletin A300–26–6030, Revision 02, dated April 4, 1997; and Airbus Service Bulletin A320–26–1037, Revision 02, dated July 8, 1997; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Airbus AOT 26–12, Revision 1, dated July 4, 1994, was approved previously by the Director of the Federal Register as of March 17, 1995 (60 FR 11619, March 2, 1995).

(3) Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directives 96–186–204(B)R1, dated January 15, 1997, and 96–007–073(B), dated January 3, 1996.

(f) This amendment becomes effective on October 21, 1998.

Issued in Renton, Washington, on September 9, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–24657 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–50–AD; Amendment 39–10758; AD 98–14–51]

RIN 2120–AA64

Airworthiness Directives; CFM International CFM56–7B Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule, request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting Airworthiness Directive (AD) T98–14–51 that was sent previously to all known U.S. owners and operators of CFM International CFM56–7B series turbofan engines by individual telegrams. This AD requires checks of the Accessory Gearbox (AGB)/Transfer Gearbox (TGB) Magnetic Chip Detector (MCD) for abnormal magnetic particles that indicate a pending starter gearshaft failure, and, removal from service of suspect starter gearshafts and replacement with serviceable parts. This amendment is prompted by reports of 2 inflight engine shutdowns due to uncontained failures of the AGB starter gearshafts. The actions specified by this AD are intended to prevent a dual inflight engine shutdown event, which could result in a forced landing and loss of the aircraft.

DATES: Effective October 1, 1998, to all persons except those persons to whom it was made immediately effective by telegraphic AD T98–14–51, issued July 2, 1998, which contained the requirements of this amendment.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 1, 1998.

Comments for inclusion in the Rules Docket must be received on or before November 16, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–ANE–50–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ad-engineprop@faa.dot.gov''. Comments sent via the Internet must contain the docket number in the subject line.

The applicable service information may be obtained from CFM International, Technical Publications Department, 1 Neumann Way, Cincinnati, OH 45215; telephone (513) 552–2981, fax (513) 552–2816. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Glorianne Messemer, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7132, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: On July 2, 1998, the Federal Aviation Administration (FAA) issued telegraphic airworthiness directive (AD) T98–14–51, applicable to CFM International (CFMI) CFM56–7B series turbofan engines, which requires checks of the Accessory Gearbox (AGB)/ Transfer Gearbox (TGB) Magnetic Chip Detector (MCD) for abnormal magnetic

particles that indicate a pending starter gearshaft failure, and, removal from service of suspect starter gearshafts and replacement with serviceable parts. That action was prompted by reports of 2 inflight engine shutdowns on CFM56–7B series turbofan engines installed on Boeing 737–700 series aircraft. The cause of the inflight engine shutdowns were due to uncontained failures of the AGB starter gearshafts. The investigation revealed that the gearshafts failed due to inadequate fatigue capability caused by high residual tensile stresses introduced during the manufacturing process, coupled with the elimination of shotpeening in the gearshaft hub. The manufacturing process has since been modified. The starter gearshaft, part number (P/N) 340–055–202–0, involved in the events are part of a lot of 237 parts manufactured. All of the production engines currently in revenue service or as spares incorporate these suspect starter gearshafts. The engines have been identified by engine serial number (ESN) in Table 1 of CFMI CFM56–7B Service Bulletin (SB) No. 72–130, dated June 29, 1998, and the suspect starter gearshafts have also been identified by serial number (S/N) in that table. Currently, all revenue service Boeing 737–700 and 737–800 series aircraft have the suspect starter gearshafts installed in both engines; therefore, this condition, if not corrected, could result in a dual inflight engine shutdown event, which could result in a forced landing and loss of the aircraft.

The FAA has reviewed and approved the technical contents of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, that describes procedures for removal from service of suspect starter gearshafts and replacement with serviceable parts; and CFMI CFM56–7B SB No. 72–132, dated July 2, 1998, that describes procedures for checks of the AGB/TGB MCD for abnormal magnetic particles that indicate a pending starter gearshaft failure.

Since the unsafe condition described is likely to exist or develop on other engines of the same type design, the FAA issued Telegraphic AD T98–14–51 to prevent a dual inflight engine shutdown event. The AD requires, prior to further flight, a check of the AGB/TGB MCD on the No. 2 engine of the aircraft for abnormal magnetic particles that indicate a pending starter gearshaft failure. If abnormal magnetic particles are discovered, this AD requires, prior to further flight, removal from service of the starter gearshaft and replacement with a serviceable part not identified by S/N in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998. The required actions are required for the No. 2 engine first because the AGB is located on the inboard side of the No. 2 engine. An uncontained starter gearshaft failure on the No. 2 engine would expose the aircraft to a higher risk of damage than an uncontained starter gearshaft failure on the No. 1 engine. This AD also requires, on the next calendar day after checking the No. 2 engine of the aircraft, an AGB/TGB MCD check of the No. 1 engine of the aircraft, and, if necessary, removal from service of starter gearshafts. Thereafter, the AGB/TGB MCD checks must be alternated, every other calendar day, between the No. 2 and No. 1 engines of the aircraft.

This AD also requires, within 350 hours time in service (TIS) after the effective date of this AD, or by August 1, 1998, whichever occurs first, on aircraft with two affected engines installed identified by ESN in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, on the No. 2 engine of that aircraft, removal from service of suspect starter gearshafts and replacement with a serviceable part not identified by S/N in Table 1 of that SB. On aircraft with only one affected engine identified by ESN in Table 1 of that SB, this AD requires removal from service of suspect starter gearshafts and replacement with a serviceable part not identified by S/N in Table 1 of that SB within 725 hours TIS after the effective date of this AD, or by September 1, 1998, whichever occurs first. Installation of replacement serviceable starter gearshafts constitutes terminating action to the repetitive AGB/TGB MCD checks. The calendar end-dates were determined based upon risk analysis and parts availability.

Finally, this AD requires reporting to the Engine Certification Office of the FAA within 5 working days of replacement of the starter gearshaft; if the ESN listed in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, does not directly correspond to the adjoining starter gearshaft serial number, in order to verify that all affected parts have been removed from service. The actions are required to be accomplished in accordance with the Accomplishment Instructions in the SBs described previously.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual telegrams issued on July 2, 1998, to all known U.S. owners and operators of CFMI CFM56–7B series turbofan engines. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to § 39.13 of part 39 of the Federal Aviation Regulations (14 CFR part 39) to make it effective to all persons.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–ANE–50–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to

correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–14–51 CFM International: Amendment 39–10758. Docket 98–ANE–50–AD.

Applicability: CFM International (CFMI) CFM56–7B series turbofan engines, identified by engine serial number (ESN) in CFMI CFM56–7B Service Bulletin (SB) No. 72–130, dated June 29, 1998. These engines are installed on but not limited to Boeing 737–600, 737–700, and 737–800 series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a possible dual inflight engine shutdown event, which could result in a forced landing and loss of the aircraft, accomplish the following:

(a) Prior to further flight, check the accessory gearbox (AGB)/transfer gearbox (TGB) magnetic chip detector (MCD) on the No. 2 engine of the aircraft for abnormal magnetic particles that indicate a pending starter gearshaft failure, in accordance with CFMI CFM56–7B SB No. 72–132, dated July 2, 1998, as follows:

(1) If magnetic particles are found to be abnormal in accordance with CFMI CFM56–7B SB No. 72–132, dated July 2, 1998, prior to further flight, remove from service starter gearshafts, part number (P/N) 340–055–202–0, and replace with a serviceable part not identified by S/N in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998.

(2) On the next calendar day after checking the No. 2 engine of the aircraft, perform an AGB/TGB MCD check of the No. 1 engine of the aircraft, and, if necessary, remove from service starter gearshafts and replace with serviceable parts in accordance with paragraph (a)(1) of this AD.

(3) Thereafter, perform AGB/TGB MCD checks alternately, every other calendar day, between the No. 2 and No. 1 engines of the aircraft, and, if necessary, remove from service starter gearshafts and replace with serviceable parts in accordance with paragraph (a)(1) of this AD.

(b) Within 350 hours time in service (TIS) after the effective date of this AD, or by August 1, 1998, whichever occurs first, on aircraft with two affected engines installed identified by ESN in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, remove from service suspect starter gearshafts on the No. 2 engine and replace with a serviceable part not identified by S/N in Table 1 of that SB.

(c) Within 725 hours TIS after the effective date of this AD, or by September 1, 1998, whichever occurs first, on aircraft with only one affected engine identified by ESN in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, remove from service suspect starter gearshafts and replace with a serviceable part not identified by S/N in Table 1 of that SB.

(d) Installation of serviceable starter gearshafts not identified by S/N in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, constitutes terminating action to the repetitive AGB/TGB MCD checks required by paragraph (a) of this AD.

(e) Report to the Manager of the Engine Certification Office of the FAA within 5 working days of replacement of the starter gearshaft if the ESN listed in Table 1 of CFMI CFM56–7B SB No. 72–130, dated June 29, 1998, does not directly correspond to the adjoining starter gearshaft serial number to verify that all affected parts have been removed from service. The address is: Manager, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; fax (781) 238–7199. Reporting requirements have been approved by the Office of Management and Budget and assigned OMB control number 2120–0056.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(g) The actions required by this AD shall be accomplished in accordance with the following CFMI SBs:

Document No.	Pages	Date
CFM56–7B SB No. 72–130.	1–33	June 29, 1998.
Total pages: 33.		
CFM56–7B SB No. 72–132.	1–12	July 2, 1998.
Total pages: 12.		

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from CFM International, Technical Publications Department, 1 Neumann Way, Cincinnati, OH 45215; telephone (513) 552–2981, fax (513) 552–2816. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective October 1, 1998, to all persons except those persons to whom it was made immediately effective by telegraphic AD T98–14–51, issued July 2, 1998, which contained the requirements of this amendment.

Issued in Burlington, Massachusetts, on September 8, 1998.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 98–24644 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 736

[Docket No. 980821223–8223–01]

RIN 0694–AB74

Establishment of 24-Month Validity Period for Certain Reexport Authorizations and Revocation of Other Authorizations

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration is amending the Export

Administration Regulations (15 CFR parts 730–774) by issuing General Order No. 1 establishing a 24-month validity period for all reexport authorizations that do not contain any license validity period and revoking those that have been in effect for more than 24 months.

DATES: This rule is effective September 16, 1998.

ADDRESSES: Written comments on this rule should be sent to Hillary Hess, Director, Regulatory Policy Division, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Hillary Hess, Director, Regulatory Policy Division, Bureau of Export Administration, Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

On March 25, 1996 (61 FR 12714), the Bureau of Export Administration (BXA) issued completely revised Export Administration Regulations (EAR). Among other things, the new regulations established a general rule that all licenses for export or reexport would be limited to a 24-month validity period and established procedures for seeking extensions (§ 750.7(g)).

The general practice before June 15, 1996, under the previous regulations, was to issue reexport authorizations for most countries without a set validity period. Since requests for reexport authorizations specified the items to be reexported, the parties to the transaction, and the dollar value involved, the reexport authorizations were available for as long as was necessary to complete the transaction(s) in question. In addition, a number of reexport authorizations issued after June 15, 1996, did not include a specific validity period.

BXA is issuing this general order to bring any outstanding reexport authorizations which were issued without validity periods in line with the general 24-month validity period established in the new regulations.

This order revokes all outstanding reexport authorizations issued with no validity period before the 24-month period preceding September 16, 1998 to a country that has been designated by the Secretary of State as a country that has repeatedly provided support for acts of international terrorism, effective September 16, 1998. Designated terrorist-supporting countries currently are Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria. All other outstanding reexport authorizations issued with no validity period within the 24-months preceding September 16, 1998 will be revoked November 16, 1998. Reexport authorizations issued with no validity period within 24-months preceding September 16, 1998 will expire 24-months from the date of issuance of the reexport authorization or November 16, 1998, which ever is longer. Extensions of any such reexport authorizations may be requested prior to the effective date of this action in accordance with the procedures set forth in § 750.7(g). Should BXA provide specific notice to a reexporter of an earlier revision, suspension, or revocation date for such reexport authorization, then the information in the specific notice from BXA shall be controlling.

The term ''authorization'' as used in this rule encompasses the range of reexport authorizations granted by BXA, which includes licenses, individual letters, and other types of notifications.

The Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect the EAR and, to the extent permitted by law, the provisions of the EAA in Executive Order 12924 of August 19, 1994, as extended by the President's notices of August 15, 1995 (60 FR 42767), August 14, 1996 (61 FR 42527), August 13, 1997 (62 FR 43629) and August 13, 1998 (63 FR 44121).

Saving Clause

Shipments of items under reexport authorizations revoked as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard carrier to a port of export pursuant to actual orders for export before September 16, 1998 may be exported in accordance with the terms of the previous reexport authorization provisions up to and including September 30, 1998. Any such items not actually exported before midnight September 30, 1998, require a new license in accordance with this regulation.

Rulemaking Requirements

1. This interim rule has been determined to be not significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This rule involves collection of information requirements subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694–0088.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this interim rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

List of Subjects in 15 CFR Part 736

Exports, Foreign trade.

Accordingly, part 736 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

PART 736—[AMENDED]

1. The authority citation for part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*, 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228 (1997); Notice of August 15, 1995, 3 CFR, 1995 Comp. 501 (1996); Notice of August 14, 1996, 61 FR 42527, 3 CFR 1996 Comp., p. 298 (1997); Notice of August 13, 1997 (62 FR 43629, August 15, 1997); and Notice of August 13, 1998 (62 FR 44121, August 17, 1998).

2. Supplement No. 1 to part 736 is revised to read as follows:

Supplement No. 1 To Part 736—General Orders

General Order No. 1 of September 16, 1998; Establishing a 24-month validity period on reexport authorizations issued without a validity period and revoking those exceeding that period.

(a) Reexport authorizations issued within 24-months of the General Order. All reexport authorizations issued with no validity period within the 24-months preceding September 16, 1998 shall be deemed to have an expiration date which shall be the date 24-months from the date of issuance of the reexport authorization or November 16, 1998, whichever is longer.

(b) Reexport authorizations issued before the 24-month period preceding the General Order. For reexport authorizations issued with no validity period before the 24-month period preceding September 16, 1998:

(1) Effective September 16, 1998, all such outstanding reexport authorizations for terrorist-supporting countries (see parts 742 and 746 of the EAR) are revoked.

(2) Effective November 16, 1998, all other such outstanding reexport authorizations are revoked.

(c) *Extensions.* If necessary, you may request extensions of such authorizations according to procedures set forth in § 750.7(g) of the EAR.

(d) *Specific Notice from BXA.* If you have received, or should you receive, specific notice from BXA with regard to a reexport authorization covered by this General Order, informing you of a revocation, suspension, or revision (including validity period) of any such reexport authorization, then the terms of that specific notice will be controlling.

(e) *Definition of ''authorization''.* The term ''authorization'' as used in this General Order encompasses the range of reexport authorizations granted by BXA, which includes licenses, individual letters, and other types of notifications.

Dated: September 10, 1998.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 98–24829 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 904

[SPATS No. AR–030–FOR]

Arkansas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving an amendment to the Arkansas regulatory program (hereinafter referred to as the ''Arkansas program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Arkansas proposed revisions to, and additions of, regulations pertaining to definitions; reclamation plans; disposal of excess spoil; steep slope mining; permits incorporating variances from approximate original contour restoration requirements for steep slope mining; prime farmlands; performance standards for coal exploration and prime farmland; signs and markers; topsoil and subsoil; hydrologic balance; backfilling and grading; procedures for assessment conference; and request for adjudicatory public hearing. Arkansas intends to revise its program to be consistent with the corresponding Federal regulations and to enhance enforcement of its program.

EFFECTIVE DATE: September 16, 1998.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135–6548, Telephone: (918) 581–6430; e-mail address: mwolfrom@mcrgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Arkansas Program

On November 21, 1980, the Secretary of the Interior conditionally approved Arkansas' program. You can find background information on Arkansas' program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the November 21, 1980, **Federal Register** (45 FR 77003). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 904.10, 904.12, 904.15, and 904.16.

II. Submission of the Proposed Amendment

In a letter dated February 6, 1998 (Administrative Record No. AR–561), Arkansas sent us a proposed amendment to its program in accordance with SMCRA. The proposed amendment responded to our June 17, 1997, letter (Administrative Record No. AR–559) that we sent to Arkansas in accordance with 30 CFR 732.17(c). The amendment also included changes made at Arkansas' own initiative.

We announced receipt of the proposed amendment in the February 26, 1998, **Federal Register** (63 FR 9747). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the proposed amendment. The public comment period closed on March 30, 1998. Because no one requested a public hearing or meeting, we did not hold one.

During our review of the amendment, we identified concerns relating to Arkansas' regulations at the Arkansas Surface Coal Mining and Reclamation Code (ASCMRC) 816.56, Hydrologic Balance: Postmining Rehabilitation of Sediment Ponds, Diversions, Impoundments, and Treatment Facilities; ASCMRC 816.102, Backfilling and Grading: General Grading Requirements; ASCMRC 823.11, Applicability; and minor typographical errors. We notified Arkansas of these concerns in a fax dated July 6, 1998 (Administrative Record No. AR–561.06).

In a letter dated July 15, 1998 (Administrative Record No. AR–561.07), Arkansas responded to our concerns by sending us additional explanatory information and revisions to its proposed program amendment. Arkansas proposed additional revisions to ASCMRC 701.5, Definitions; ASCMRC 780.14, Operation Plan: Maps and Plans; ASCMRC 816.46, Hydrologic Balance: Siltation Structures; ASCMRC 816.56, Hydrologic Balance: Postmining Rehabilitation of Sediment Ponds, Diversions, Impoundments, and Treatment Facilities; ASCMRC 816.102, Backfilling and Grading: General Grading Requirements; ASCMRC 823.11, Applicability; and ASCMRC 823.15, Revegetation and Restoration of Soil Productivity. Throughout its regulations, Arkansas also changed the name of the old U.S. Soil Conversation Services to its new name of Natural Resources Conservation Service.

Based upon the additional explanatory information and/or revisions to the proposed program amendment submitted by Arkansas, we reopened the public comment period in the August 4, 1998, **Federal Register** (63 FR 41506). The public comment period closed on August 19, 1998.

III. Director's Findings

Following, and in accordance with SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are our findings concerning the proposed amendment.

Any revisions that we do not specifically discuss below concern nonsubstantive wording changes, or revised cross-references and paragraph notations to reflect organizational changes that result from this amendment.

A. Regulations That Arkansas Removed From the Arkansas Surface Coal Mining and Reclamation Code

1. ASCMRC 701.5, Definitions and ASCMRC 816.46, Hydrologic Balance: Siltation Structures

Arkansas' current definition of ''siltation structure'' at ASCMRC 816.46(a)(1) only applies to section 816.46. The definition of ''siltation

structure'' must also apply to siltation structures at ASCMRC 780.25, Reclamation Plan: Siltation Structures, Impoundments, Banks, Dams and Embankments. Therefore, Arkansas proposed to remove the definition of ''siltation structure'' from section 816.46(a)(1) and reserve paragraph (a)(1), and add the definition of ''siltation structure'' to the general definition section of its regulations at ASCMRC 701.5, Definitions. We are approving the removal of this definition from section 816.46(a)(1) and its addition to section 701.5 because we removed the definition of ''siltation structure'' from our own regulation at 30 CFR 816/817.46(a)(1) and added it to 30 CFR 701.5. We made the changes in recognition of the broader applicability of ''siltation structure'' under the revised impoundment regulations. (See 59 FR 53022, October 20, 1994.)

2. ASCMRC 816.21, Topsoil: General Requirements; ASCMRC 816.23, Topsoil: Storage; ASCMRC 816.24, Topsoil: Redistribution; ASCMRC 816.25, Topsoil: Nutrients and Soil Amendments

Arkansas proposed to remove ASCMRC 816.21, 816.23, 816.24 and 816.25 from its regulations and combine their provisions into fully revised ASCMRC 816.22. We are approving the removal of the above sections because we removed the counterpart Federal regulations at 30 CFR 816/817.21, 816/817.23, 816/817.24, and 816/817.25 from our regulations and incorporated their provisions into 30 CFR 816/817.22. (See 48 FR 22092, May 16, 1983.)

3. ASCMRC 816.103, Backfilling and Grading: Covering Coal and Acid and Toxic Forming Materials and ASCMRC Part 826, Special State Program Performance Standards—Operations on Steep Slopes

Arkansas proposed to remove ASCMRC 816.103 and Part 826 from its regulations and incorporate their essential provisions into ASCMRC 816.102(f) and 816.106, respectively. We are approving the removal of these sections because we removed the counterpart Federal regulations at 30 CFR 816.103 and Part 826, respectively, from our regulations and incorporated their essential provisions into 30 CFR 816.102(f), and 816.107 and 817.107, respectively. (See 48 FR 23356, May 24, 1983.)

B. Revisions to Arkansas' Regulations That Are Substantively Identical to the Corresponding Provisions of the Federal Regulations

1. Arkansas proposed to change the name of the ''U.S. Soil Conservation Service'' to its new name of ''Natural Resources Conservation Service'' throughout its regulations. We find that these changes will not make the Arkansas regulations less effective than the Federal regulations.

2. The proposed State regulations listed in the table below contain language that is the same as or similar to the corresponding sections of the Federal regulations. Any differences between the proposed State regulations and the Federal regulations are nonsubstantive.

Topic	State regulation (ASCMRC)	Federal counterpart regulation (30 CFR)
Definition of ''Significant recreational, timber, economic or other values compatible with surface coal mining operations''.	761.5	761.5.
Operation Plan: Maps and Plans	780.14(c)	780.14(c).
Disposal of Excess Spoil	780.35(b)	780.35(b).
Prime Farmland	785.17(d)(5)	785.17(e)(5).
Topsoil and Subsoil	816.22	816.22.
Hydrologic Balance: Postmining Rehabilitation of Sedimentation Ponds, Diversions, Impoundments, and Treatment Facilities.	816.56	816.56.
Disposal of Excess Spoil: Pre-existing Benches	816.74	816.74.
Backfilling and Grading: General Grading Requirements	816.102	816.102.
Backfilling and Grading: Thin Overburden	816.104–S	816.104.
Backfilling and Grading: Thick Overburden	816.105–S	816.105.
Backfilling and Grading: Steep Slopes	816.106	816.107.
Special State Program Performance Standards—Operations on Prime Farmland	Part 823	Part 823.
Procedures for Assessment Conference	845.18(b)	845.18(b).
Request for Adjudicatory Public Hearing	845.19(a)	845.19(a)

Because the above proposed revisions are identical in meaning to the corresponding Federal regulations, we find that Arkansas' proposed regulations are no less effective than the Federal regulations.

C. Revisions to Arkansas' Regulations That Are Not Substantively Identical to the Corresponding Provisions of the Federal Regulations

1. ASCMRC 780.25, Reclamation Plan: Siltation Structures, Impoundments, Banks, Dams and Embankments

Except for all coal processing waste dams and embankments covered by Section 816.81 through 816.84, Arkansas' current regulation at paragraph (a)(3)(i) authorizes a registered land surveyor to prepare and certify detailed design plans for structures not included in paragraph (a)(2). In this amendment, Arkansas removed the language that authorizes a registered land surveyor to prepare and certify these detailed design plans. We approve the removal of this authorization because 30 CFR 780.25(a)(3)(i) allows the preparation and certification of the above mentioned detailed design plans only in States that authorize land surveyors to prepare and certify such plans. Arkansas' regulations do not authorize land surveyors to prepare or certify such plans. Therefore, the removal of this provision does not conflict with 30 CFR 780.25(a)(3)(i).

IV. Summary and Disposition of Comments

Public Comments

We solicited public comments on the proposed amendment, but did not receive any.

Federal Agency Comments

According to 30 CFR 732.17(h)(11)(i), and in a letter dated February 18, 1998 (Administrative Record No. AR–561.03), we solicited comments on the proposed amendment from various Federal

agencies with an actual or potential interest in Arkansas' program. We received comments from the U.S. Army Corp of Engineers in two letters dated March 17, 1998, and August 11, 1998 (Administrative Record Nos. AR–561.05 and AR–561.12, respectively). Both letters stated that they are satisfied with the changes that Arkansas proposed to make to the Arkansas program.

Environmental Protection Agency (EPA)

According to 30 CFR 732.17(h)(11)(ii), we are required to obtain the written consent of the EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards that are in force under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Arkansas proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not request the EPA's consent.

According to 30 CFR 732.17(h)(11)(i), we solicited comments on the proposed amendment from the EPA (Administrative Record No. AR–561.01). The EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

According to 30 CFR 732.17(h)(4), we are required to solicit comments from the SHPO and ACHP on proposed amendments which may have an effect on historic properties. We solicited comments on the proposed amendment from the SHPO and ACHP (Administrative Record No. AR–561.02), but neither responded to our request.

V. Director's Decision

Based on the above findings, we approve the amendment as submitted to us by Arkansas on February 6, 1998, and as revised on July 15, 1998.

We approve the regulations that Arkansas proposed with the provision that they be fully placed in force in identical form to the regulations submitted to and reviewed by OSM and the public.

To implement this decision, we are amending the Federal regulations at 30 CFR Part 904 which codifies decisions concerning the Arkansas program. We are making this final rule effective immediately to expedite the State program amendment process and to encourage Arkansas to bring the Arkansas program into conformity with the Federal standards without undue delay. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12866

The Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review) exempts this rule from review.

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

This rule does not require an environmental impact statement since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Unfunded Mandates

OSM has determined and certifies under the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of $100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 904

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 31, 1998.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

For the reasons set out in the preamble, 30 CFR Part 904 is amended as set forth below:

PART 904—ARKANSAS

1. The authority citation for Part 904 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 904.15 is amended in the table by adding a new entry in chronological order by ''Date of final publication'' to read as follows:

§ 904.15 Approval of Arkansas regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* * *	* * *	* * * * *
February 6, 1998	September 16, 1998	ASCMRC 701.5; 761.5(d); 780.14(c); 780.18(b)(7), .25(a)(3)(i), .35(b); 785.15(b)-(c), .16(a), (c)(6), and (d), .17(d)(5); 815.15(k); 816.11(g), .21, .22, .23, .24, .25, .43(e), (f)(5), .44(c), .46, .48(b), .56, .74, .102, .103, .104-S, .105-S, .106, .107(a)-(b); Part 823; Part 826; 845.18(b) and .19(a).

[FR Doc. 98–24780 Filed 9–15–98; 8:45 am]
BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 934

[SPATS ND–032–FOR, Amendment No. XXII]

North Dakota Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the North Dakota regulatory program (hereinafter referred to as the ''North Dakota program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions and information explaining those North Dakota's proposed rules and statutes which comprise the amendment pertain to: the North Dakota Small Operator Assistance Program, and individual civil and criminal penalties within the coal exploration section of the program. The amendment is intended to revise the North Dakota program to be consistent with the corresponding Federal regulations and SMCRA.

EFFECTIVE DATE: September 16, 1998.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–6550; Fax: (307) 261–6552; Internet: GPadgett@osm.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Program

On December 15, 1980, the Secretary of the Interior conditionally approved the North Dakota program. General background information on the North Dakota program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the North Dakota program can be found in the December 15, 1980, **Federal Register** (45 FR 82214). Subsequent actions concerning the North Dakota program and program amendments can be found at 30 CFR 934.12, 934.13, 934,15, and 934.16.

II. Proposed Amendment

By letter dated April 12, 1995, North Dakota submitted a proposed amendment (amendment number XXII, administrative record No. ND–W–01) to its program pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). North Dakota submitted the proposed amendment in response to the required program amendments at 30 CFR 934.16(y) and (z) (59 FR 37423, 37428–374296; July 22, 1994). The statutory provisions North Dakota proposed to revise are: North Dakota Century Code (NDCC) 38–14.1–37(4) concerning SOAP, reimbursement of costs, and NDCC 38–12.1–08, concerning coal exploration, individual civil and criminal penalties.

OSM announced receipt of the proposed amendment in the May 2, 1995, **Federal Register** (60 FR 21484; administrative record No. ND–W–04), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment. Because no one requested a public hearing or meeting, none was held. The public comment period ended at 4 p.m. on June 1, 1995.

During its review of the amendment, OSM identified concerns with the proposed revisions to NDCC 38–13.1–08, relating to individual civil and criminal penalties within the coal exploration program. OSM notified North Dakota of the concerns by letter dated August 28, 1995 (administrative record No. ND–W–12). North Dakota responded in a letter dated October 19, 1995 (administrative record No. ND–W–14) by submitting additional proposed revisions to its program at North Dakota Administrative Code 43–02–01 and additional explanatory information pertaining to North Dakota Century Code 38–12.1–08.

Based upon the revisions to and additional explanatory information that was submitted with the proposed program amendment submitted by North Dakota, OSM reopened the public comment period in the November 9, 1995, **Federal Register** (60 FR 56549; administrative record No. ND–W–16). The public comment period ended 4 p.m. November 24, 1995.

The regulatory revisions that North Dakota proposed in its October 19, 1995 letter, while satisfying most of OSM's concerns, made North Dakota's regulations at North Dakota Administrative Code (NDAC) 43–02–01 inconsistent with its statute at NDCC 38–12.1–08, upon which those regulations are based. However, when this was pointed out to North Dakota in a July 30, 1997 telephone conversation (administrative record No. ND–W–21), it submitted an August 1, 1997 letter (administrative record No. ND–W–18) slightly revising its regulations at NDAC 43–02–01 to make them consistent with its statute. Based on the proposed revision, OSM reopened the public comment period in the September 4, 1997, **Federal Register** (62 FR 46695; administrative record No. ND–W–19). The public comment period ended 4 p.m. September 19, 1997.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 732.15 and 732.17, finds that the proposed program amendment submitted by North Dakota on April 12, 1995, and as revised and supplemented with additional explanatory information and program revisions on October 19, 1995, and on August 1, 1997, with additional requirements, is no less stringent than SMCRA and no less effective than the Federal regulations. Accordingly, the Director approves the proposed amendment.

1. NDCC 38–.1–37(4): Small Operators

North Dakota proposed a revision to NDCC 38–14.1–37(4), pursuant to the Director's Findings at III.3.i that were contained in the July 22, 1994 **Federal Register** (Vol. 59, No. 140, p. 37426). This addition of subsection 4 to NDCC 38–14.1–37 also affects subsections 2 and 3 in accordance with the July 22, 1994, **Federal Register** noted above. The Director's Findings at III.3.h. states that:

> [I]f North Dakota ultimately decides to adopt the responsibility to provide or assume the training costs and inform qualified coal operators of the availability of assistance under SOAP, NDCC 38–14.1–37(3), because

of its discretionary nature, will be less stringent than section 507(c)(2) of SMCRA. North Dakota will then be required to amend its program to mandate that the Commission ''shall'' provide or assume the costs of training and inform qualified coal operators of the availability of assistance under SOAP.

North Dakota has not yet decided whether to provide or assume the training costs and inform qualified coal operators under SOAP (August 25, 1998 telephone conversation, administrative record No. ND–W–24). As stated in the July 22, 1998 **Federal Register**, if North Dakota ultimately decides to adopt the responsibility to provide or assume the training costs and inform qualified coal operators of the availability of assistance under SOAP, NDCC–14.1–37(3), because of its discretionary nature, will be less stringent than section 507(c)(2) of SMCRA. North Dakota will then be required to amend its program to mandate that the Commission ''shall'' provide or assume the costs of training and inform qualified coal operators of the availability of assistance under SOAP. Based on the aforementioned, the Director finds that the proposed addition to North Dakota's statute, NDCC 38–14.1–37(4), is no less stringent than SMCRA.

2. NDCC 38–12.1–08 and 12.1–03–03: Coal Exploration, Statutory Provisions Regarding Individual Civil and Criminal Penalties

In previous reviews of the North Dakota program, OSM found deficiencies relating to the imposition of civil and/or criminal penalties on individual officers, agents, and directors of a corporation where the corporation committed a violation of the coal exploration program. A required amendment was consequently codified at 30 CFR 934.16(y) (57 FR 807, 827; January 9, 1992), and was subsequently modified (59 FR 37423, 37432; July 22, 1994). The modified required amendment, codified at 30 CFR 934.16(y), required North Dakota to amend NDCC 38–12.1–08 to specifically address the circumstances under which a corporate director, officer, or agent may be individually subject to civil or criminal penalties in connection with a violation committed by a corporate permittee. North Dakota was also required to submit proposed revisions in NDCC 38–12.1–08 to provide that (in addition to violations) failure or refusal to comply with the orders listed in section 518(f) of SMCRA and issued by the North Dakota Industrial Commission serve as an additional basis for the imposition of individual civil and criminal penalties upon corporate officers, directors, and agents.

North Dakota proposed in this amendment to add a new provision at NDCC 38–12.1–08(3) stating that:

> Any corporation or any person who controls the activity of a corporation who violates this chapter or any permit condition or rule implementing this chapter [NDCC Chapter 38–12.1] is subject to a civil penalty not to exceed five thousand dollars per day of such violation.

In addition, North Dakota re-proposed the revisions to NDCC 38–12.1–08(1) and (2) that were not approved in the July 22, 1994, rulemaking. In its August 28, 1995, letter (administrative record No. ND–W–12) identifying concerns to this amendment, OSM found that the proposed new provision at NDCC 38–12.1–08(3) essentially repeated the provision of NDCC 38–12.1–08(1) and did not clarify that individuals (officers, directors, and agents of corporate permittees) may be subject to penalties where the corporation, as opposed to the individual, commits a violation. In its October 19, 1995, response (administrative record No. ND–W–14), North Dakota argued that State law a NDCC 12.1–03–03 (as well as NDCC 38–12.1–08(3), does subject directors, officers, and agents to civil and criminal penalties even though it is the corporation, not the individuals, that committed a violation.

A. Criminal Penalties

With regard to the criminal penalties, North Dakota also referred to the provisions of NDCC 12.1–03–03 in its October 19, 1995 letter. NDCC 12.1–03–03 provides:

12.1–03–03 Individual accountability for conduct on behalf of organizations

1. A person is legally accountable for any conduct he performs or causes to be performed in the name of the organization or in its behalf to the same extent as if the conduct were performed in his own name or on his behalf.

2. Except as otherwise expressly provided, whenever a duty to act is imposed upon an organization by a statute or regulation thereunder, any agent of the organization having primary responsibility for the subject matter of the duty is legally accountable for an omission to perform the required act to the same extent as if the duty were imposed directly upon himself.

The terms ''agent'' and ''organization,'' as used in NDCC 12.1–03–03(2), are defined at NDCC 12.1–03–04(1) as follows:

> In this chapter: (a) ''Agent'' means any partner, director, officer, governor, manager, servant, employee, or other person authorized to act in behalf of an organization. (b) ''Organization'' means any legal entity, whether or not organized as a corporation, limited liability company, or unincorporated association, but does not include an entity organized as or by a governmental agency for the execution of a governmental program.

Since ''organization'' includes corporations, and ''agent'' includes officers and directors of corporations, NDCC 12.1–03–03(1) would, when a corporation commits a violation, subject the officers, directors, and agents of the corporation to the same criminal penalties as the corporation, provided the individuals had ''performed'' or ''caused to be performed'' the conduct. OSM finds no substantive differences between the NDCC 12.1–03–03(1) phrase ''performs or causes to be performed'' and the SMCRA 518(f) phrase ''authorized, ordered, or carried out'' identifying the applicable conduct.

NDCC 12.1–03–03(2) would subject the individuals to the same criminal penalties as the corporation in the case of a failure or refusal to act if the individual had ''primary responsibility'' for that duty. North Dakota pointed out in its October 19, 1995, letter that NDCC 38.12–1–04(3) authorizes the Industrial Commission of North Dakota to promulgate and enforce orders, and that a failure or refusal to comply with all types of such orders would also constitute a violation of ''this chapter,'' as used in NDCC 38–12.1–08.

North Dakota's proposed addition of the phrase ''or willfully'' to subsection (2) of NDCC 38–12.1–08 would extend individual criminal penalties to cases where the individual's conduct is willful or knowing, rather than simply ''knowingly,'' as the statute previously read. For a discussion of North Dakota's definitions of ''knowing'' and ''willful,'' see 59 FR 37423, 37428–37429; July 22, 1994. North Dakota's provision, as proposed, and as pointed out in its October 19, 1995, letter, would also subject individuals (whether or not corporate officers acting for a corporation) to criminal penalties for knowingly reporting false information.

North Dakota's existing provision at NDCC 38–12.1–08(2), and the re-proposed revision to it, when read in conjunction with the newly proposed provisions at NDCC Chapter 12.1–03, provide for individual criminal penalties against corporate officers in all of the situation in which individual criminal penalties are authorized under SMCRA Section 518(f). Since failure or refusal to comply with any order of the Commission would be included as a violation, without the few exceptions granted in SMCRA Section 518(e) and (f), individuals might be subject to penalties for still more actions or omission than required by SMCRA

Section 518, and therefore North Dakota's statute is no less stringent than SMCRA. In addition, individuals would be subject to criminal penalties for knowingly reporting false information in all of the situations in which individuals are subjected to such criminal penalties under SMCRA Section 518(g).

B. Civil Penalties

North Dakota's proposed new paragraph at NDCC 38–12.1–08(3), while similar to the first paragraph, NDCC 38–12.1–08(1), goes beyond it in that it applies to ''Any corporation or any person who controls the activity of a corporation who violates this chapter.'' The corporation or person's conduct need not be willful or knowing. The term, ''any person,'' refers to a ''director, officer, or agent or a corporate permittee'' and is intended by the State to be broader in its coverage than simply attempting to list the position of everyone to whom the paragraph might apply (7/8, 9/98 telephone conversations, administrative record No. ND–W–22).

To make North Dakota regulations consistent with the North Dakota statute, in a August 1, 1997 revision, North Dakota changed ''willfully *and* knowingly'' to ''willfully *or* knowingly'', thereby strengthening the scienter requirement so that it could apply to more cases than those in SMCRA or the Federal regulations.

Based on the above discussion, the Director finds that North Dakota's proposed statutory revisions at NDCC 38–12.1–08 to be no less stringent than SMCRA Section 518(f) and (g), and is approving the proposed revisions and additions. The Director also finds that the approval of this amendment satisfies both parts of the required amendment at 30 CFR 934.16(y). Therefore, he is removing that required amendment.

3. NDAC 43–02–01: Coal Exploration, Individual Civil Penalties, Regulatory Provisions (SMCRA 518(f))

In a previous review of the North Dakota coal exploration program and proposed amendments to that program, OSM found that the program lacked regulations imposing civil and/or criminal penalties on individual officers of a corporation when the corporation commits a violation of the coal exploration program (59 FR 37423, 37428–37429; July 22, 1994). A requirement for North Dakota to amend the program was codified at 30 CFR 934.16(z) (59 FR 37423, 37432; July 22, 1994), which required revision of NDAC 43–02–01–05 to specifically address the circumstances under which a corporate director, officer, or agent maybe individually subject to civil or criminal penalties in connection with a violation committed by a corporation. In response to this amendment requirement, North Dakota in its October 19, 1995 letter, and as modified in its August 1, 1997 letter, proposed the following addition to its regulations at NDAC 43–02–01:

(1) Whenever a corporate permittee violates a condition of a permit, or any other rule or regulation imposed under this chapter and NDCC 38–12.1, or fails or refuses to comply with an order issued by the commission pursuant to NDCC 38–12.1–04(3), or any order incorporated in a final decision issued by the commission, except an order incorporated in a decision requiring the payment of a penalty, any director, officer, or agent of such corporation who willfully or knowingly authorized or carried out such violation, failure, or refusal shall be held accountable, and the commission shall enforce the civil and criminal penalties provided against the corporation and the corporate directors, officers, and agents when the corporation commits such violation, failure, or refusal, as provided by law.

(2) A civil penalty may be assessed by the commission as authorized by NDCC 38–12.1–08 only after the person or persons have been given an opportunity for public hearing pursuant to the procedures specified in NDCC Ch. 28–32.

(3) Any civil penalties assessed may be recovered by the commission in a civil action in the North Dakota district court for the county in which the violation occurred or in which the party assessed has his or her residence or principal office in the state.

Proposed paragraph (1) of NDAC 43–02–01 tracks the language of SMCRA 518(f). The proposal would specify that all violations of the coal exploration program are (in the defined circumstances) subject to individual penalties; in SMCRA 518(f), it states that ''Whenever a corporate permittee violates a condition of a permit * * *.'' In addition, the proposed North Dakota regulation states that the corporate officers ''shall be held accountable,'' and therefore individually liable for criminal and civil penalties. Moreover, the proposed regulatory language further states that the Commission shall enforce the program's civil and criminal penalties against both the corporation and the corporate officers.

Regarding failures or refusals to comply, the proposed language specifies that all corporate officers who willfully or knowingly authorized or carried out the failure or refusal shall be held accountable, not only those corporate officer(s) with ''primary responsibility'' for that aspect of the operation; this language extends the reach to corporate officers subject to individual penalties for failure or refusal to comply to the same degree provided under SMCRA Sections 518(e) and (f). The proposed regulatory language also exempts from individual penalties failure or refusal to comply with orders incorporated in decisions requiring the payment of a penalty, as do SMCRA 518(e) and (f). The proposed North Dakota regulatory language also specifically addresses the circumstances under which a corporate director, officer, or agent may be individually subject to civil or criminal penalties in connection with a violation, failure, or refusal committed by a corporation.

Proposed paragraph (2) of NDAC 43–02–01 is substantively the same as the first sentence of SMCRA 518(b), and thus provides for the same due process appeals for individual civil penalties as does SMCRA 518(f) (by referencing 518(b)).

Proposed paragraph (3) of NDAC 43–02–01 provides for the recovery of individual civil penalties through civil actions, to the same extent as SMCRA 518(d).

Based on the above discussion, the Director finds the proposed rules at NDAC 43–02–01 (1) through (3) to be no less stringent than SMCRA Sections 518(b), (d), (e), and (f) regarding authorization for and procedures for individual civil and criminal penalties. The approval of this proposal would also satisfy the required program amendment codified at 30 CFR 934.16(z) (59 FR 37423, 37432; July 22, 1994). The Director is therefore removing this required program amendment.

IV. Summary and Disposition of Comments

Following are summaries of all substantive written comments on the proposed amendment that were received by OSM, and OSM's responses to them.

1. Public Comments

OSM invited public comments on the proposed amendment in the May 2, 1995 **Federal Register** (60 FR 21484; administrative record No. ND W–04), the November 9, 1995 **Federal Register** (69 FR 56549; administrative record No. ND–W–16), and the September 4, 1997, **Federal Register** (62 FR 46695; administrative record No. ND–W–19), but no comments were received.

2. Federal Agency Comments

Pursuant to 732.17(h)(11)(i), OSM solicited comments from various Federal agencies with an actual or potential interest in the North Dakota program and in the proposed amendment in an April 20, 1995, letter (administrative record No. ND–W–03), a

November 9, 1995 **Federal Register** notice (60 FR 56549; administrative record No. ND–W–16), and a September 4, 1997 **Federal Register** notice (62 FR 46695; administrative record No. ND–WS–19).

The Agricultural Research Service of the U.S. Department of Agriculture responded on May 5, 1995 that it had no comment or additions to the amendment (administrative record No. ND–W–05).

The U.S. Army Corps of Engineers responded on May 9, 1995 that it ''found the changes to be satisfactory to our agency'' (administrative record No. ND–W–07).

The Bureau of Indian Affairs responded on May 12, 1995 that ''[w]e have no objections to the amendment because it does not affect Indian Lands'' (administrative record No. ND–W–08).

Rural Economic and Community Development of the U.S. Department of Agriculture responded on May 23, 1995 that it had no comment (administrative record No. ND–W–09).

The Mine Safety and Health Administration (MSHA) of the U.S. Department of Labor responded on June 2, 1995 that the amendment ''appears not to conflict with any MSHA regulations'' (administrative record No. ND–W–11)).

3. Environmental Protection Agency (EPA) Concurrence and Comments

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to solicit the written concurrence of EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that North Dakota proposed to make in its amendment pertain to air or water quality standards. However, OSM requested EPA's comments on April 20, 1995 (administrative record No. NDW–03 with the proposed amendment (administrative record No. ND W–01). EPA did not respond to OSM's request.

4. State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Pursuant to 30 CFR 732.17(h)(4), OSM solicited comments on the proposed amendment from the SHPO and ACHP (administrative record No. ND W–03). Neither the SHPO nor the ACHP responded to OSM's request.

V. Director's Decision

Based on the aforementioned findings, the Director approves the proposed amendment as submitted on April 12, 1995, and as supplemented with additional explanatory information and regulations on October 19, 1995, and August 1, 1997, as discussed in:

Finding No. 1, NDCC 38–14.1–37(4), the statute that specifies that under certain circumstances a coal mine operator who received assistance for permitting or training reimburse the State of North Dakota for the costs of that assistance;

Finding No. 2, NDCC 38–12.1–08, the statute in which is added the term, ''or willfully'' to its existing language, ''who knowingly violates this chapter, or any permit condition or regulation implementing this chapter,'' and references NDCC 12.1–03–03, which makes a person legally accountable for any conduct he performs or causes to be performed in the name of an organization or in its behalf to the same extent as if the conduct were performed in his own name or his behalf;'' and

Finding No. 3, NDAC 43–02–01, the regulation imposing individual civil and criminal penalties on individual officers of a corporation when the corporation commits a violation of the coal exploration program.

The Federal regulations at 30 CFR Part 934, codifying decisions concerning the North Dakota program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive order 12866 (Regulatory Planning and Review).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by Section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that Section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

3. National Environmental Policy Act

An environmental impact statement is not required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

5. Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 934

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 1, 1998.

Richard J. Seibel,

Regional Director, Western Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 934—NORTH DAKOTA

1. The authority citation for Part 934 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 934.15 is amended, as depicted in the table below, by adding a new entry in chronological order by ''Date of Final Publication'' to read as follows:

§ 934.15 Approval of North Dakota regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* *	* *	* * *
April 12, 1995	September 16, 1998	Statute: NDCC 38–14.1–37(4); NDCC 38–12.1–08; Rule: NDAC 43–02–01.

3. Section 934.16 is amended by removing and reserving paragraphs (y) and (z).

[FR Doc. 98–24781 Filed 9–15–98; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 122–4078c; FRL–6160–8]

Approval and Promulgation of Air Quality Implementation Plans; Commonwealth of Pennsylvania; Interim Final Determination that Pennsylvania Continues to Correct the Deficiencies of its Enhanced I/M SIP Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: Elsewhere in today's **Federal Register**, EPA has published a direct final rule granting full conditional approval of the Commonwealth of Pennsylvania's enhanced motor vehicle inspection and maintenance (I/M) program, under section 348 of the National Highway System Designation Act of 1995 (NHSDA) and section 110 of the Clean Air Act (CAA). Based on the approval, EPA is making an interim final determination, by this action, that the Commonwealth has continued to correct the deficiency prompting the original disapproval of the Pennsylvania enhanced I/M SIP revision. This action will defer the application of the offset sanction which would have been implemented on August 29, 1998, and defers the future application of the highway sanction. Although this action is effective upon publication, EPA will take comment on this interim final determination as well as EPA's approval of the Commonwealth's submittal. EPA will publish a final action taking into consideration any comments received on EPA's direct final rule and this interim final action.

DATES: Effective dates September 16, 1998.

COMMENTS: Comments must be received by October 16, 1998.

ADDRESSES: Comments should be mailed to Marcia Spink, Associate Director, Office of Air Programs, Mail code 3AP20, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street—14th Floor, Philadelphia, Pennsylvania 19103; and at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, (215) 814–2176, at the EPA Region III address above; or via e-mail at rehn.brian@epa.gov. While information may be requested via e-mail, comments must be submitted in writing to the EPA Region III address above.

SUPPLEMENTARY INFORMATION:

I. Background

Pennsylvania's March 1996 I/M SIP Revision Approval Status

By means of an April 13, 1995 letter, EPA notified Pennsylvania that the conditional approval of the Pennsylvania enhanced I/M SIP revision, approved in August of 1994, had been converted to a disapproval (60 FR 47084). The letter triggered the 18-month time clock for the mandatory application of sanctions under section 179(a) of the CAA. That 18-month sanctions clock expired on October 13, 1996. On March 22, 1996, the Commonwealth of Pennsylvania submitted an enhanced I/M SIP revision to EPA, requesting action under the NHSDA of 1995 and the CAA. On June 27, 1996 and July 29, 1996, supplements to the March 22, 1996 SIP revision were officially submitted to EPA.

On October 3, 1996, EPA proposed in the **Federal Register** (61 FR 51598) conditional approval, on an interim basis for an 18-month period, of a SIP submitted by the Commonwealth in March 1996. That proposed SIP approval was granted under authority of the National Highway Systems Designation Act of 1995 (NHSDA) and the Clean Air Act (CAA). EPA simultaneously issued an interim final determination action in the **Federal Register** (61 FR 51598), which deferred the imposition of the 2:1 offset sanction upon new or modified sources seeking permits under section 173 of the CAA. The 2:1 offsets sanction would otherwise have been automatically imposed upon Pennsylvania on October 13, 1996. Since EPA had received a SIP submittal from the Commonwealth of Pennsylvania for its enhanced I/M program in March of 1996, and since EPA proposed approval of that SIP revision on October 3, 1996, EPA believed the October 3, 1996 interim final determination to defer sanctions was justified. EPA concluded at that time that it was more than likely than not that Pennsylvania had corrected the deficiency which had initiated the sanctions clock, and therefore, did not believe sanctions were warranted simply because EPA had insufficient time to complete its final rulemaking action to approve the Commonwealth's March 1996 I/M program SIP revision. On January 28, 1997, EPA issued in the **Federal Register**, final interim conditional approval of the Commonwealth's March 1996 SIP revision (62 FR 4004).

On November 13, 1997, February 24, 1998, and August 21, 1998, Pennsylvania submitted formal revisions to its enhanced I/M program SIP. The purpose of these SIP revisions was to remedy deficiencies identified by EPA in its January 28, 1997 (62 FR 4004) interim conditional approval of Pennsylvania's enhanced I/M program SIP. It also served to transmit

Pennsylvania's demonstration of the effectiveness of its decentralized testing program (compared to a centralized program) in achieving the emissions reductions credits claimed by Pennsylvania in its SIP, required under section 348 of the National Highway Systems Designation Act.

On August 11, 1998, EPA signed a direct final rulemaking action to approve the Commonwealth's November 1997 and February 1998 SIP revisions, which addressed several of the deficiencies identified by EPA in its January 28, 1997 (62 FR 51638) interim conditional approval of the Commonwealth's enhanced I/M SIP.

EPA's Current Rulemaking Actions

In the Final Rules section of today's **Federal Register**, EPA has taken direct final rulemaking action to approve the Commonwealth's NHSDA network effectiveness demonstration, and to approve the Commonwealth's SIP revisions submitted to remedy the deficiencies identified by EPA in its January 28, 1997 interim conditional approval (61 FR 51638). EPA simultaneously issued, in the Proposed Rules section of today's **Federal Register**, a document proposing to take the same action upon the Commonwealth's SIP revision in the event EPA receives adverse comments on the direct final rule.

EPA believes that, as a result of today's related rulemaking actions, that it is more likely than not that the March 22, 1996 enhanced I/M SIP revision, as supplemented on June 27, 1996, July 29, 1996, November 1, 1996, November 13, 1997, February 24, 1998, and August 21, 1998 (hereafter referred to as ''the I/M SIP revision''), continues to remedy the SIP deficiency triggering the sanctions clock for the duration of EPA's rulemaking process on this I/M SIP revision. This interim determination will not halt or reset the sanctions deadline, but will continue to defer the implementation of sanctions until either: EPA's January 28, 1998 conditional approval is converted to a disapproval, or the Commonwealth's enhanced I/M SIP is fully approved.

Today EPA is also providing the public with an opportunity to comment on this interim final determination. If, based on any comments received by EPA upon this interim final determination action and any comments on EPA's approval of the Commonwealth's I/M SIP revision, EPA determines that the SIP revision is not approvable and this final action was inappropriate, EPA will take further action to disapprove the Commonwealth's I/M SIP revision. If EPA's approval of the Pennsylvania I/M SIP revision is not finalized, then sanctions would be applied as required under section 179(a) of the CAA and 40 CFR 52.31.

II. EPA Action

Based on the approval set forth elsewhere in today's **Federal Register**, EPA believes that it is more likely than not that the Commonwealth has corrected the deficiencies that prompted the original disapproval of the Pennsylvania enhanced I/M SIP for which the April 13, 1995 finding of failure to submit was issued. Therefore, EPA concludes that sanctions should continue to be stayed for the duration of Pennsylvania's conditional SIP approval.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

III. Administrative Requirements

Because EPA has preliminarily determined that the March 22, 1996 Pennsylvania I/M SIP revision is conditionally approvable, relief from future sanctions should be provided as quickly as possible. Therefore, EPA is invoking the good cause exception under the Administrative Procedure Act (APA) in not providing an opportunity for comment before this action takes effect.[1] 5 U.S.C. 553(b)(B). The EPA believes that notice-and-comment rulemaking before the effective date of this action is impracticable and contrary to the public interest. The EPA has reviewed the Commonwealth's March 1996 I/M SIP revision (including all subsequent SIP revisions). Through this interim final determination action, the Agency believes that it is more likely than not that the Commonwealth has continued to correct the deficiency for which the sanctions clock was started (i.e., failure on the part of the Commonwealth's to have an approved enhanced I/M SIP under sections 182 and 184 of the Clean Air Act).

Therefore, it is not in the public interest to initially apply sanctions when the Commonwealth has most likely corrected the deficiency that triggered the sanctions clock. Moreover, it would be impracticable to go through notice-and-comment rulemaking on a finding that the Commonwealth has corrected the deficiency prior to the rulemaking approving the Commonwealth's enhanced I/M SIP revision. Therefore, EPA believes that it is necessary to use the interim final rulemaking process to defer sanctions while EPA completes its rulemaking process on the approvability of the Commonwealth's I/M SIP revision. In addition, EPA is invoking the good cause exception to the 30-day notice requirement of the APA because the purpose of this notice is to relieve a restriction. *See* 5 U.S.C. 553(d)(1).

A. Executive Orders 12866 and 13045

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review. The final rule is not subject to E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks,'' because it is not an ''economically significant'' action under E.O. 12866.

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that

[1] As previously noted, however, by this action EPA is providing the public with a chance to comment on EPA's determination after the effective date and EPA will consider any comments received in determining whether to reverse such action.

imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

D. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. EPA's approval action today maintains conditional approval status, granted by EPA in January 1997. Approval of a SIP submittal under section 110 and subchapter I, part D of the CAA does not create any new requirements but simply approves requirements that a state is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. (Union Electric Co. v. U.S. EPA, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2)).

E. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

F. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

G. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this direct final approval action for Pennsylvania's enhanced I/M SIP revision must be filed in the United States Court of Appeals for the appropriate circuit by November 16, 1998. Filing a petition for reconsideration by the Administrator of this interim final determination does not affect the finality of this rule pertaining to the Pennsylvania enhanced I/M SIP for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. §§ 7401–7671q.

Dated: August 28, 1998.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 98–24731 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 122–4078a; FRL–6160–6]

Approval and Promulgation of Air Quality Implementation Plans; Commonwealth of Pennsylvania; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action approves an August 21, 1998 State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania to supplement its enhanced motor vehicle emissions inspection and maintenance (I/M) program SIP. The August 21, 1998 SIP revision submittal addresses the seven remaining minor, or *de minimus*, deficiencies cited in EPA's January 28, 1997 conditional interim approval of Pennsylvania's enhanced I/M program. In addition, Pennsylvania submitted a demonstration of the effectiveness of its decentralized network required under the National Highway Systems Designation Act of 1995 (NHSDA). The intended effect of this action is to remove all remaining de minimus conditions imposed by EPA in its January 28, 1997 conditional interim approval of Pennsylvania's March 1996 enhanced I/M SIP revision, and to approve the Commonwealth's decentralized network effectiveness demonstration. EPA is hereby removing the interim approval status of the Commonwealth's I/M SIP, granted under the NHSDA. However, as Pennsylvania must still provide specific information related to one condition of the January 28, 1997 approval of its enhanced I/M program, the

Commonwealth's enhanced I/M SIP remains conditionally approved under the Clean Air Act.

DATES: This direct final rule is effective on November 16, 1998, without further notice, unless EPA receives adverse comment by October 16, 1998. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Comments should be mailed to Marcia Spink, Associate Director, Office of Air Programs, Mailcode 3AP20, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street—14th Floor, Philadelphia, Pennsylvania 19103; and at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, (215) 814–2176, or by e-mail at rehn.brian@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 28, 1997, EPA published in the **Federal Register** a final rulemaking action (62 FR 4004) granting conditional interim approval to Pennsylvania's enhanced I/M program SIP revision, submitted March 22, 1996, under the authority of both the NHSDA and the Clean Air Act as amended in 1990. The NHSDA established key changes to previous EPA I/M requirements. Under the NHSDA, EPA could not disapprove, or automatically discount the effectiveness of, a state's I/M program solely because it utilized a decentralized testing network. Instead, on the basis of a ''good faith estimate'' by a state, the NHSDA allowed for presumptive equivalency of such decentralized networks to the benchmark of centralized programs. Under section 348 of the NHSDA, EPA was required to grant ''interim'' approval to such decentralized programs, for an 18-month period, at the end of which each affected state must submit an evaluation of the actual effectiveness of the enhanced program.

In Pennsylvania's case, EPA granted interim approval of the enhanced I/M program SIP, pursuant to Section 348 of the NHSDA, but also conditioned approval of that SIP upon the satisfaction of five major deficiencies and fourteen *de minimus* deficiencies. EPA's January 28, 1997 conditional interim approval stipulated that the five major conditions must be corrected within one year of final interim approval, and that the *de minimus* conditions be addressed within eighteen months of final interim approval. On January 9, 1998, EPA published (63 FR 1362) a final rule amending federal I/M requirements for ongoing evaluation methodologies for state I/M programs—one of the major deficiencies of Pennsylvania's program identified by EPA in its January 1998 interim conditional approval. EPA's I/M requirements rule change also served to amend the related condition of the Commonwealth's approval. As a result, the deadline for the Commonwealth to satisfy this condition was extended from February 28, 1998 to November 30, 1998.

Pursuant to EPA's January 28, 1997 rulemaking action, in order for the Commonwealth's SIP to be eligible for full approval, all *de minimus* conditions placed by EPA upon the Commonwealth's SIP must be remedied by the end of the 18-month interim approval period. The Commonwealth's NHSDA program effectiveness demonstration was due to be completed and submitted to EPA within the same time frame. The interim approval period for Pennsylvania expires August 28, 1998.

On September 2, 1998, EPA published a direct final rulemaking action (DFR), which is separate from today's action. The purpose of that rulemaking action is to approve two Pennsylvania SIP revisions, which addressed four major and seven de minimus rulemaking conditions from EPA's January 28, 1997 conditional interim approval. EPA anticipates that the DFR published on September 2, 1998 will become effective (barring adverse comment) within 60 days of its publication date. The subject of today's rulemaking action is the Commonwealth's August 21, 1998 SIP revision which addresses the remaining seven de minimus conditions and the network design effectiveness demonstration.

II. Summary of Pennsylvania's August 21, 1998 SIP Revision Submittal

On August 21, 1998, the Commonwealth of Pennsylvania submitted a revision to its SIP. In addition, on August 21, 1998 the Commonwealth submitted its I/M program network effectiveness demonstration. The SIP revision submittal also consists of contractual materials related to enhanced I/M oversight and program management services contract. These include the program oversight contract with the Commonwealth's I/M program manager, MCI Telecommunications Corporation (MCI) in addition to portions of the Commonwealth's request for proposal (RFP) and portions of the contractor and subcontractor proposal responses. The SIP submittal also includes certain contract exhibits, relevant to the satisfaction of federal requirements applicable to the remaining de minimus conditions set forth in 40 CFR 52.2026. Finally, the SIP submittal contains some Pennsylvania state government procedures and other miscellaneous forms and documents.

Also on August 21, 1998, the Commonwealth submitted its demonstration of the effectiveness of its decentralized program network (pursuant to the requirements of section 348 of the NHSDA) in order to qualify for the full ''credits'' claimed by Pennsylvania for the decentralized testing format of its enhanced I/M program. Such a demonstration is required (from states that chose to submit SIPs in March of 1996 to take advantage of NHSDA flexibility granted for decentralized I/M programs) at the end of the 18-month NHSDA interim approval period. The NHSDA demonstration is to be based upon the results of data collected during operation of the enhanced I/M program.

The Commonwealth's August 21, 1998 SIP submittal is meant to address those seven remaining *de minimus* deficiencies identified by EPA in its January 28, 1997 interim conditional approval, which the Commonwealth had not yet addressed in any other I/M-related SIP revisions previously submitted to EPA.

III. EPA's Review of Pennsylvania's August 21, 1998 SIP Revision Submittal

EPA views the Commonwealth's August 21, 1998 SIP revision as a separate, independent SIP amendment from all previous enhanced I/M SIP revisions—including the Commonwealth's original, March 22, 1996 NHSDA SIP revision. While Pennsylvania's August 21, 1998 SIP revision is related to the March 1996 submittal, as well as to other later Pennsylvania enhanced I/M-related SIP revisions submitted by the Commonwealth, it serves to supplement the Commonwealth's enhanced I/M program SIP—not to replace it. Therefore, EPA has placed this revision in a separate rulemaking docket from all previous Pennsylvania enhanced I/M SIP revisions, and EPA is today acting only upon the August 21, 1998 SIP

revision. In doing so, EPA is not reopening its January 27, 1997 final rulemaking granting conditional interim approval of the Commonwealth's enhanced I/M SIP.

A. National Highway Systems Designation Act Demonstration

1. Summary of Pennsylvania's Demonstration

Pursuant to section 348 of the NHSDA, in June of 1996 Pennsylvania submitted a ''good faith estimate'' to support its claims for 100% of the credit for its decentralized, test-and-repair program, when compared to a centralized, test-only network. EPA approved the Commonwealth's ''good faith estimate'', under authority of the NHSDA, on January 28, 1997 (62 FR 4004). Pennsylvania commenced its enhanced I/M program in October of 1997, and between October 1997 to April 1998, over 2,700 stations in the Pittsburgh and Philadelphia areas were brought into the enhanced I/M program. By the end of April of 1998, Pennsylvania's operating stations had successfully completed approximately 1.7 million enhanced emissions tests.

Section 348 of the NHSDA required Pennsylvania to submit a demonstration, based upon program data collected during the interim approval period, to support its good faith estimate and to demonstrate that the credits claimed for the decentralized program were appropriate. On August 21, 1998, Pennsylvania submitted a report to EPA, entitled ''National Highway Systems Designation Act Good Faith Estimate, Description of Program Effectiveness'', that describes the Commonwealth's efforts to ensure that the program is operating as effectively as originally proposed.

Pennsylvania's demonstration is partitioned into three sections. The first section describes the program implementation status. The second section reiterates the Commonwealth's NHSDA ''good faith estimate,'' originally submitted to EPA in June of 1996. The final section describes the steps Pennsylvania has made to implement the commitments made in the good faith estimate, and provides the program data that Pennsylvania has gathered during the interim approval period to support the good faith estimate.

In general, the Commonwealth's demonstration supplies data to substantiate its emission reduction credit claims, including: an overview of number the stations conducting tests; information of individual emissions inspectors; a comparison of bar-coded vs. manual VIN entry methods as a database quality assurance measure; a summary of the state's overt and covert audit efforts; a summary of remedial activities triggered by audits; examples of the automated station record auditing performed monthly by the state and sorted by various relevant parameters; and program summary data from the start-up period of the program.[1]

As described above, Pennsylvania's demonstration contains program summary data for the period between October 1997 and April 1998. The data includes a summary of test results (stratified by vehicle model year) from inspection stations in both program areas. Specifically, this includes: the number of tailpipe tests performed using acceleration simulation mode (ASM) test method and the number performed using the two-speed idle test method, the number of vehicles initially passing and failing the applicable tailpipe test, the number of vehicles initially failing the gas cap test, and the number of vehicles initially failing the visual inspection. For vehicles initially failing the ASM tailpipe test, the results are further segregated by those failing for excessive hydrocarbon or carbon monoxide emissions versus those failing for nitrogen oxides (NO_x) emissions. Finally, the Commonwealth's demonstration contains similar data for the first retest performed on vehicles that failed the initial test. The resultant data indicates that, for the period from October of 1997 to April of 1998, the overall Pennsylvania program failure rate for that period was approximately 10%. For that period, approximately 31% of all 1970s model year vehicles, 21% of all 1980s vehicles, and 5% of all 1990s vehicles failed the applicable ASM or two-speed idle tailpipe, or the gas cap check and visual inspection. Of the approximately 160,000 vehicles that initially failed testing during that period, approximately 36% passed a retest within 30 days.

The demonstration also contains data on the Commonwealth's quality assurance efforts to maintain the integrity of the decentralized testing network, for the period from October 1997 to April of 1998. This information includes the results of over 2,900 overt audits performed by Pennsylvania's program manager contractor, MCI—1,625 for the Philadelphia program area and 1,286 for the Pittsburgh program area. Overt audits may include such checks as: checks of station/inspector compliance with administrative/record keeping requirements, oversight of inspector testing, and/or reference gas analyzer calibration (referred to hereafter as overt audits). Every emissions inspection station in Pennsylvania has received at least one overt audit. In addition, five-point gas audits are performed at least semi-annually upon every emission analyzer at every licensed test station. The Commonwealth also performs regular, monthly record audits of every licensed station, which entail a computerized review of a station's and/or inspector's testing records/results. This information is sorted to focus on station performance related to certain testing elements, and then analyzed for trends that would warrant an overt or a covert audit. These record audits can be done without the station even knowing, through the Commonwealth's computerized test record database. The Commonwealth also encourages consumers to request a referee test to double check tests performed by inspectors.

The Commonwealth also provided information on the results of over 1,000 covert audits conducted over this period—567 in Philadelphia and 482 in Pittsburgh. Covert audits entail an undercover visit to a station by a program compliance officer, in an unmarked car, to witness how testing is actually performed at testing stations. The results of the Commonwealth's overt and covert audits are included in the demonstration, and constitute a summary of specific violations of state requirements, as noted by state auditors. Information on the Commonwealth's use of this audit information is also included in the demonstration. Violations identified during record review audits or overt or covert audits are addressed by the Commonwealth either through compliance assistance or through formal enforcement actions. For the period from January 1, 1998 to July of 1998, 742 potential violations were referred for enforcement action. Of those, 406 were remedied through mandatory, 3-hour training classes to educate inspectors on conducting proper testing. Through July, Pennsylvania conducted over 220 hearings, with 129 pending adjudication. As a result of hearings, 97 stations were provided compliance assistance by the Commonwealth, six received written warnings, and 23

[1] Pennsylvania cautions that this data used in support its program effectiveness was gathered during start-up and phase-in period of the program. The data is based upon less-stringent phase-in test standards, and is affected by other aspects of the program that are being phased in over the first program cycle, such as: repair technician training requirements, phased-in limits for the cost of testing waivers, and program enforcement that is directed heavily towards the use of compliance assistance as a means to educate inspectors and repair technicians.

stations were assessed compliance points, fines, and/or suspensions. The Commonwealth intends to hold over 90 hearings in the next several months to deal with outstanding violations. As a result of the Commonwealth's compliance assistance effort in response to I/M program violations, the Commonwealth intends to extend its use to all inspectors participating in the enhanced I/M program.

2. EPA's Analysis of Pennsylvania's NHSDA Demonstration

The Commonwealth's good faith estimate from June 10, 1996 indicated the Commonwealth's commitment to design and operate a program with safeguards in place to limit improper testing in its test-and-repair network. Pennsylvania's ''good faith estimate'' listed numerous program elements which would be developed and implemented to ensure that its decentralized enhanced I/M program would achieve the predicted results. These enhancements to Pennsylvania's existing basic I/M program were designed to ensure the proper testing and repair of vehicles, and to discourage the circumvention of program requirements by inspectors. These measures included: a stringent oversight program making extensive use of overt and covert audits, the use of State Police for more visible station/inspector enforcement, the ability to collect and to analyze real-time data from decentralized stations, and improvements to automate station data input activities (e.g., through the use of bar code readers). EPA believes that these measures do provide a means to deter improper testing in the Commonwealth's enhanced program, in comparison to the Commonwealth's previously existing decentralized I/M program.

EPA believes that the demonstration proves that the Commonwealth's qualitative assessment of its program can serve as a means for EPA to determine whether the decentralized program deserves the full credits associated with a similar centralized program. EPA therefore believes that the Commonwealth's data collected during the interim approval period, and compiled in the state's August 1998 NHSDA demonstration, indicate that the credits claimed by the Commonwealth for its decentralized program network are appropriate.

EPA believes that the variety of data supplied encompasses those implementation issues that most significantly impact program effectiveness. The summary of test results also will allow EPA to determine whether the Commonwealth's experience deviates greatly from that of other, comparable I/M programs. Using its experience with such programs—and taking into consideration the fact that Pennsylvania's program is less than a year old and therefore is still in the process of correcting the sort of start-up problems that all new programs experience—EPA concludes that approval of the Pennsylvania's I/M program is appropriate at this time.

B. Review of the SIP for Satisfaction of the Remaining De Minimus Deficiencies

The conditions that EPA has placed upon its interim approval of Pennsylvania's SIP are codified at 40 CFR 52.2026. On September 2, 1998, EPA published a DFR approving two Pennsylvania SIP revisions (63 FR 46664)—submitted on November 13, 1997 and February 24, 1998. Barring adverse public comment, the DFR will be effective sixty days from its publication date. Once effective, this action will strike four of the major conditions and seven of the de minimus conditions at 40 CFR 52.2026 (a) and (b). Specifically it will eliminate conditions (1), (3), (4), and (5), currently codified at 40 CFR 52.2026(a) and de minimus deficiencies (2), (3), (4), (6), (11), (12), and (13), currently codified at 40 CFR 52.2026(b).

The deficiencies addressed by the Commonwealth's August 21, 1998 SIP revision [ordered below as they appear at 40 CFR 52.2026(b)], include the following de minimus conditions:

(1) The final I/M SIP submittal must detail the number of personnel and equipment dedicated to the quality assurance program, data collection, data analysis, program administration, enforcement, public education and assistance, on-road testing and other necessary functions as per 40 CFR 51.354;

(5) The final I/M SIP submittal must provide quality control requirements for one-mode ASM (or two-mode ASM if the Commonwealth opts for it);

(7) The final I/M SIP submittal must include the RFP, or other legally binding document, which adequately addresses how the private vendor selected to perform motorist compliance enforcement responsibilities for the Commonwealth's program will comply with the requirements as per 40 CFR 51.362;

(8) The final I/M SIP submittal must include the RFP that adequately addresses how the private vendor will comply with 40 CFR 51.363, a procedures manual which adequately addresses the quality assurance program and a requirement that annual auditing of the quality assurance auditors will occur as per 40 CFR 51.363(d)(2);

(9) The final I/M SIP submittal must include provisions to maintain records of all warnings, civil fines, suspensions, revocations, violations and penalties against inspectors and stations, per the requirements of 40 CFR 51.364;

(10) The final I/M SIP submittal must include the RFP, or other legally binding document, which adequately addresses how the private vendor selected by the Commonwealth to perform data collection and data analysis and reporting will comply with all the requirements of 40 CFR 51.365 and 40 CFR 51.366; and

(14) The final I/M SIP submittal must contain sufficient information to adequately address the on-road test program resource allocations, methods of analyzing and reporting the results of the on-road testing and information on staffing requirements for both the Commonwealth and the private vendor for the on-road testing program.

The Commonwealth's August 21, 1998 submittal contains contractual materials that address and remedy all of the approval conditions listed above. EPA's detailed analysis of the August 21, 1998 SIP revision and its rationale for determining that these conditions have been satisfied is provided in a technical support document (TSD) prepared by EPA in support of this action. That document is available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this action.

III. EPA's Rulemaking Action

EPA has reviewed the Commonwealth's August 21, 1998 SIP revision and has determined that this SIP revision adequately remedies the seven de minimus rulemaking conditions listed in the above section of this action. EPA is approving the Commonwealth's August 21, 1998 SIP submittal as having satisfied those de minimus conditions set forth previously in this document. The purpose of this approval action is to remove those de minimus conditions (codified at 40 CFR 52.2026(b)) imposed by EPA's January 28, 1997 conditional interim approval of the Commonwealth's enhanced I/M SIP. This action also serves to approve Pennsylvania's demonstration of the effectiveness of its decentralized vehicle emissions testing program. EPA believes that the Commonwealth's data and supporting information to bolster its ''good faith estimate'' measures demonstrate that the emissions reductions credits claimed by the Commonwealth for its enhanced I/M SIP are appropriate.

EPA imposed fourteen de minimus conditions in its January 28, 1997 interim conditional approval of the Pennsylvania enhanced I/M SIP revision, submitted by Pennsylvania to EPA in March of 1996. As previously stated, EPA published a DFR on September 2, 1998 approving I/M-related SIP revisions submitted by the Commonwealth on November 13, 1997 and February 24, 1998. That DFR removes seven of those de minimus conditions, while today's direct final rulemaking action (approving the Commonwealth's August 21, 1998 SIP) serves to remove the seven remaining *de minimus* conditions. As indicated in EPA's January 1997 interim conditional approval, Pennsylvania needed to satisfy all the de minimus deficiencies by the end of the interim approval period (i.e., by August 28, 1998). Today's direct final rulemaking action, coupled with the direct final rulemaking published on September 2, 1998, serves to remove all of the de minimus conditions. EPA is also approving, by today's action, the Commonwealth's program network effectiveness demonstration, as required under the NHSDA. Because the Commonwealth has submitted an approvable demonstration and remedied all de minimus requirements, EPA is acting today to remove the interim approval status of the Commonwealth's I/M SIP.

However, as Pennsylvania must still provide specific information by November 30, 1998 to address one of the conditions imposed by EPA's January 28, 1997 conditional approval under the Clean Air Act (i.e., the Commonwealth's choice of an EPA-approved methodology for conducting an on-going I/M program evaluation), the Commonwealth's enhanced I/M SIP remains conditionally approved under the Clean Air Act.

As a result of the above actions, EPA is today granting final conditional approval to the Pennsylvania enhanced I/M program SIP, under the authority granted under section 110 of the Clean Air Act.

Today's action removes interim approval status from the Commonwealth's enhanced I/M SIP. With the exception of the condition requiring the Commonwealth to provide specific information, by November 30, 1998 (with regard to its chosen methodology for performing its on-going enhanced I/M program evaluation) both today's DFR and EPA's September 2, 1998 DFR serve to approve SIP revision submittals which address the conditions imposed in EPA's January 28, 1997 conditional approval of the Commonwealth's enhanced I/M SIP under the Clean Air Act.

Final Action

EPA is approving the Commonwealth's August 21, 1998 SIP submittal as having fully satisfied seven de minimus conditions identified by EPA in its January 28, 1997 interim conditional approval of the Pennsylvania enhanced I/M SIP (62 FR 4004). EPA is also approving the Commonwealth's demonstration, submitted for the purpose of proving that the credits granted for the Commonwealth's decentralized I/M program testing network were appropriate, based upon data collected from operation of the Commonwealth's enhanced I/M program. On the basis of the data contained in the Commonwealth's demonstration, EPA believes that Pennsylvania has sufficiently demonstrated that its decentralized program is capable of achieving emissions reductions similar to those associated with a similarly designed, centralized program.

On September 2, 1998, EPA published a DFR approving I/M-related SIP revisions. Once effective, it removes four conditions placed upon the Commonwealth's enhanced I/M program SIP (as codified at 40 CFR 52.2026), as well as seven de minimus conditions. Today's direct final rulemaking action to approve the Commonwealth's August 1998 SIP revision removes the seven remaining *de minimus* conditions imposed upon the Commonwealth's enhanced I/M program SIP (as codified at 40 CFR 52.2026).

If EPA receives adverse comments related to the removal of these *de minimus* deficiencies, during either the comment period provided in today's DFR action or that of the September 2, 1998 DFR action, EPA will publish a timely withdrawal of today's direct final rule and will inform the public that the rule will not take effect. All public comments received on both rulemaking actions will then be addressed in a subsequent rule based upon the proposed rule. Again, EPA will not institute a second public comment period upon either this, or the September 2, 1998 rule.

Today's action removes the interim status of the Commonwealth's enhanced I/M SIP approval. Pennsylvania must provide specific information to address one remaining Clean Air Act condition, set forth at 40 CFR 52.2026(a)(2), the Pennsylvania enhanced I/M SIP continues to be conditionally approved under section 110 of the Clean Air Act.

For the purpose of clarity and to avoid confusion over the remaining conditions upon interim approval of Pennsylvania's plan, EPA is removing those *de minimus* conditions from 40 CFR 52.2026 which have been satisfied by the Commonwealth's August 21, 1998 SIP revision. EPA is reserving the sections of 40 CFR 52.2026 that correspond to these conditions, so as not to renumber any potentially outstanding conditions of approval listed in that section.

IV. Administrative Requirements

Nothing in EPA's rulemaking action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

A. Executive Orders 12866 and 13045

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review. The final rule is not subject to E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks,'' because it is not an ''economically significant'' action under E.O. 12866.

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of

section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

D. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. EPA's approval action today maintains conditional approval status, granted by EPA in January 1997. Approval of a SIP submittal under section 110 and subchapter I, part D of the CAA does not create any new requirements but simply approves requirements that a state is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. (*Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2)).

E. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that the approval action promulgated does not include a federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

F. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

G. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this direct final approval action for Pennsylvania's enhanced I/M SIP revision must be filed in the United States Court of Appeals for the appropriate circuit by November 16, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule pertaining to the Pennsylvania enhanced I/M SIP for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: August 28, 1998.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart NN—Pennsylvania

2. Section 52.2026 is amended by revising the introductory paragraph to read as set forth below.

3. Section 52.2026 is further amended by removing and reserving paragraphs (b) (1), (5), (7), (8), (9), (10), and (14).

§ 52.2026 Conditional approval

The Commonwealth of Pennsylvania's March 27, 1996 submittal of its enhanced motor vehicle emissions inspection and maintenance (I/M) program; as amended on June 27, 1996, July 29, 1996, November 1, 1996, November 13, 1997, February 24, 1998, and August 21, 1998; is conditionally approved pending satisfaction of paragraph (a)(2) of this section.

* * * * *

[FR Doc. 98–24730 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[FRL–6159–2]

RIN 2060–AE56

Revision of Standards of Performance for Nitrogen Oxide Emissions From New Fossil-Fuel Fired Steam Generating Units; Revisions to Reporting Requirements for Standards of Performance for New Fossil-Fuel Fired Steam Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to section 407(c) of the Clean Air Act, the EPA has reviewed the emission standards for nitrogen oxides (NO_X) contained in the standards of performance for new electric utility steam generating units and industrial-commercial-institutional steam generating units. The EPA proposed revisions to 40 CFR part 60, subparts Da and Db based on this review on July 9, 1997. The EPA received 70 public comments on the proposed rule changes. These comments were reviewed, and this document reflects the EPA's responses to the issues raised by the commenters. This action promulgates the revised standards of performance.

The final revisions change the existing standards for NO_X emissions by reducing the numerical NO_X emission limits for both utility and industrial steam generating units to reflect the performance of best demonstrated technology. The final revisions also change the format of the revised NO_X emission limit for new electric utility steam generating units to an output-based format to promote energy efficiency and pollution prevention. However, in a change from the proposed language, the EPA is revising the standard for existing utility boilers that become subject to subpart Da through modification or reconstruction to be in an equivalent input-based format.

As a separate activity, the EPA also reviewed the quarterly sulfur dioxide (SO_2), NO_X, and opacity emission reporting requirements of the utility and industrial steam generating unit regulations contained in subparts Da and Db. The final rules will allow owners or operators of affected facilities to meet the quarterly reporting requirements of both regulations by means of electronic reporting, in lieu of submitting written compliance reports.

DATES: *Effective Date:* The rule revisions are effective November 16, 1998.

Judicial Review: Under CAA section 307(b)(1), judicial review of this nationally applicable final action is available only by the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of publication of this rule. Under CAA section 307(b)(2), the regulations that are the subject of this action may not be challenged later in civil or criminal proceedings brought by EPA in reliance on them.

ADDRESSES: *Docket:* All information considered by the EPA in developing this rulemaking, including public comments on the proposed rules and other information developed by the EPA in addressing those comments since proposal, is located in Public Docket No. A–92–71 at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), 401 M Street, SW., Washington, DC 20460. The docket is located at the above address in Room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 4 p.m., Monday through Friday. Materials related to this rulemaking are available upon request from the Air and Radiation Docket and Information Center by calling (202) 260–7548 or 7549. The FAX number for the Center is (202) 260–4400. A reasonable fee may be charged for copying docket materials.

Technical Support Documents. The technical support documents that summarize information gathered during EPA's review of the subparts Da and Db NO_X standards and the public comments and EPA's responses may be obtained from the docket; from the EPA library (MD–35), Research Triangle Park, North Carolina 27711, telephone number (919) 541–2777, FAX number (919) 541–0804; or from the National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161, telephone number (703) 487–4650. Please refer to ''New Source Performance Standards, Subpart Da—Technical Support for Proposed Revisions to NO_X Standard'', EPA–453/R–94–012, ''New Source Performance Standards, Subpart Db—Technical Support for Proposed Revisions to NO_X Standard'', EPA–453/R–95–012, or ''New Source Performance Standards, Subparts Da and Db—Summary of Public Comments and Responses'', EPA–453/R–98–005.

FOR FURTHER INFORMATION CONTACT: For information concerning specific aspects of this rulemaking, contact Mr. James Eddinger, Combustion Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5426, electronic mail ''eddinger.jim@epa.gov''.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Electric utility steam generating units, Industrial steam generating units, Commercial steam generating units, and Institutional steam generating units.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that the EPA is now aware of that could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 60.40a and 60.40b of the rules. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Electronic Access and Filing Addresses

This document, the regulatory texts, and other background information are available in Docket No. A–92–71 or by request from the EPA's Air and Radiation Docket and Information Center (see **ADDRESSES**) or may be accessed through the EPA web site at: http://www.epa.gov/ttn/oarpg.

Outline

The following outline is provided to aid in locating information in this document.

I. Background

A. Statutory and Regulatory Authority

Title IV of the Clean Air Act (the Act), as amended in 1990, authorizes the EPA to establish an acid rain program to reduce the adverse effects of acidic deposition on natural resources, ecosystems, materials, visibility, and public health. The principal sources of the acidic compounds are emissions of SO_2 and NO_X from the combustion of fossil fuels. Section 407(c) of the Act requires the EPA to revise standards of performance previously promulgated under section 111 for NO_X emissions from fossil-fuel fired steam generating units, including both electric utility and nonutility units. These revised standards of performance are to reflect improvements in methods for the reduction of NO_X emissions.

The current standards for NO_X emissions from fossil-fuel fired steam generating units, which were promulgated under section 111 of the Act, are contained in the new source performance standards (NSPS) for electric utility steam generating units (40 CFR 60.40a, subpart Da) and for industrial-commercial-institutional steam generating units (40 CFR 60.40b, subpart Db).

B. Benefits of the NSPS Revisions

The revisions being promulgated reflect the Administrator's determination that the best system of NO_X emission reduction (taking into consideration the cost of achieving such emission reduction, any nonair quality health and environmental impact and energy requirements) for these sources is now reflective of flue gas treatment technologies, particularly selective catalytic reduction (SCR). The estimated decrease in baseline nationwide NO_X emissions from new, reconstructed, or modified affected sources resulting from these rule revisions remain unchanged since proposal and are approximately 23,000 Mg/year (25,800 tons/year) from utility steam generating units and 18,000 Mg/year (20,000 tons/year) from industrial steam generating units in the 5th year after proposal. This represents an approximate 42 percent reduction in the growth of NO_X emissions from new utility and industrial steam generating units subject to these revised standards. This reduction in NO_X emissions benefits public health. Nitrogen oxides can cause lung tissue damage, can increase respiratory illness, and are a primary contributor to acid rain and ground level ozone formation. The Agency's estimate of the other environmental, energy, cost, and economic impacts also are unchanged since proposal. (See 62 FR 36957 for more information on these estimates.)

In addition to direct environmental benefits, the EPA believes that the output-based format of the final rule will contribute to important national goals such as pollution prevention. One of the opportunities for pollution prevention lies in simply using energy efficient technologies to minimize the generation of emissions. These revisions promote energy efficiency at utility plants by changing the manner in which they regulate flue gas NO_X emissions. The fuel neutral format of the final rules also contributes to pollution prevention opportunities by encouraging the use of clean fuels without limiting the control options available for compliance.

A third major benefit of these revisions is that the final rules reduce the reporting burden for units subject both to NSPS subpart Da or Db and to other program(s) such as the Acid Rain or NO_X Budget Program. Therefore, the EPA will allow the SO_2, NO_X, and opacity reports currently required under subpart Da or Db to be submitted electronically in lieu of written reports. To implement this electronic reporting option, special electronic data report (EDR) record types would have to be created to accommodate the compliance information required by subparts Da and Db, and sources would be required to obtain an agreement from their EPA Regional office and State authority to use the EDR format. The use of this report form is optional.

C. Public Participation

Prior to proposal, the EPA met with industry representatives several times to discuss the data and information used to develop the proposed revisions. In addition, equipment vendors, State regulatory authorities, and environmental groups had opportunity to comment on the background information that was prepared for the proposed revisions. In addition, representatives from other EPA offices and programs have been included in the regulatory development process as members of the Work Group.

The proposed revisions were published in the **Federal Register** on July 9, 1997 (62 FR 36948). The preamble to the proposed revisions discussed the availability of technical support documents, which described in detail the information gathered during the standards review. Public comments were solicited at proposal.

To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, a public hearing was held on August 8, 1997, at Research Triangle Park, North Carolina. However, the four scheduled speakers decided to submit written comments in place of attending the hearing, so no information was presented at the hearing.

The original public comment period was from July 9, 1997 to September 8, 1997. The EPA extended the public comment period to October 8, 1997 based on requests from commenters. During the public comment period, the EPA received 70 public comment letters on the proposed rule changes. In the post-proposal period, the EPA met with several industry representatives to learn more of their concerns regarding the proposed revisions and to gather additional information in order to respond to the public comments. Records of these contacts are found in the final rulemaking docket. All of the comments have been carefully considered, and, where determined to be appropriate by the Administrator, changes have been made in the proposed standards based on the comments received.

II. Summary of Final Rules

The final standards revise the NO_X emission limits for steam generating units in subpart Da (Electric Utility Steam Generating Units) and subpart Db (Industrial-Commercial-Institutional Steam Generating Units). Only those electric utility and industrial steam generating units for which construction, modification, or reconstruction is commenced after July 9, 1997 would be affected by these revisions.

The NO_X emission limit in the final rule for newly constructed subpart Da units is 200 nanograms per joule (ng/J_O) (1.6 lb/megawatt-hour (MWh)) gross energy output regardless of fuel type. For existing sources that become subject to subpart Da through modification or reconstruction, the NO_X emission limit is 65 ng/J_I [0.15 pounds per million BTU (lb/MMBtu)] heat input. For subpart Db units, the NO_X emission limit being promulgated is 87 ng/J_I (0.20 lb/MMBtu) heat input from the combustion of natural gas, oil, coal, or a mixture containing any of these fossil fuels; however, for low heat release rate units firing natural gas or distillate oil, the current NO_X emission limit of 43 ng/J_I (0.10 lb/MMBtu) heat input is unchanged.

Compliance with the proposed NO_X emission limit is determined on a 30-day rolling average basis, which is the same requirement that was in effect prior to the revisions. The EPA has added compliance and monitoring provisions that explain how sources are to demonstrate compliance with the output-based standards. These provisions will not increase the overall burden of sources to demonstrate compliance with the standards beyond what is already required of sources in the absence of these changes.

The revisions to the quarterly SO_2, NO_X, and opacity reporting requirements of subparts Da and Db allow electronic quarterly reports to be submitted in lieu of the written reports currently required under §§ 60.49a and 60.49b. The electronic reporting option would be available to any affected facility under subpart Da or Db, including units presently regulated under those subparts. Each electronic quarterly report would be submitted no later than 30 days after the end of the calendar quarter.

The format of the electronic report would be coordinated with the permitting authority. Each electronic report would be accompanied by a certification statement from the owner or operator indicating whether compliance with the applicable emission standards and minimum data requirements was achieved during the reporting period. Owners or operators would also be required to coordinate with their EPA Regional Office and State authority to ensure that the permitting authority agrees to receive reports in the EDR format.

The EPA has determined that acid rain continuous emissions monitoring systems (CEMS) can be used as NSPS CEMS. However, all CEMS must generate reports according to the requirements of the applicable subpart. For example, the acid rain CEMS missing data procedures are not acceptable under subpart Da. Under subpart Da, emission limits during hours of invalid data must be met according to the requirements of § 60.47a(f), which would supersede the acid rain CEMS procedures.

III. Significant Comments and Changes to the Proposed Revisions

Following is a discussion of the significant comments received on the proposed revisions and the resulting changes, if any, in the final rules. The document, ''New Source Performance Standards, Subparts Da and Db—Summary of Public Comments and Responses'' (EPA 453–R–98–005) contains a more detailed summary of all of the comments and responses. It also contains the explanation for minor editorial corrections made in the final revisions.

A. Performance of NO_X Control Technology

1. Selective Catalytic Reduction (SCR)

Several commenters raised concerns that the EPA's determination that SCR represents the best demonstrated technology (BDT) is not adequate. For example, commenters stated that the EPA should not consider SCR as BDT for coal-fired industrial boilers, because it has only been installed on 7 coal-fired units in the U.S., all of which are electric utility units. In addition, none of the 200 European and Japanese units with SCR cited by the EPA are industrial units. Commenters also urged that the EPA consider the potential problems associated with SCR, including costs, catalyst poisoning, and oil ash coating the catalyst, when finalizing the NSPS. Another technical issue raised was that excess SO_3 can lead to increased downstream corrosion and negative impacts on the heat rate of the unit.

Commenters also said that the relevant technologies are immature, and that EPA has insufficient data to develop a standard that fully accounts for the variabilities inherent in operating these new technologies. Other commenters added that the reported cases of successful SCR applications are extremely limited, with success being measured on the basis of short-term performance and without cost considerations.

Commenters raised similar concerns for coal-fired utility boilers. That is, they said the technology is still in the developmental phase, and there are insufficient cases where the performance of the technology has been adequately demonstrated.

The first issue raised by several of the commenters is that EPA's determination that SCR represents BDT for a range of boiler types and operating conditions is not adequate. The EPA disagrees and believes the data base that supports the BDT decision is adequate for two reasons. First, the proposal data base resulted from an extensive review of information on the available domestic and international SCR units in use in the industry at the present time. However, in response to the comments, the EPA has obtained data from three more utility boilers that utilize SCR and represent a range of operating conditions and coal types. The first utility boiler (U.S. Generating Company's Logan plant) is a 225-megawatt pulverized-coal cogeneration facility, and is operated under cycling conditions. This facility submitted 3 months of NO_X emission data to the EPA. The analysis of these data indicate that the facility is capable of achieving the input-based NO_X standard of 65 ng/J_I (0.15 lb/MMBtu) and the revised output-based standard of 200 ng/J_O (1.6 lb/MWh) gross energy output on a 30-day rolling average. (See section III.B.3 for a discussion of the development of the revised output-based standard.) The second plant is the Birchwood Power Facility, which is a 240-megawatt cogeneration facility with cycling load that began operation in 1996. Actual, short-term test results show that the facility achieves NO_X emissions of 97 ng/J_O (0.77 lb/MWh), easily attaining the NSPS output-based standard. The third facility, Stanton Energy, is a 464-megawatt utility boiler firing bituminous coal. This facility is currently meeting its permitted emission limit of 74 ng/J_I (0.17 lb/MMBtu). If this facility were to improve the performance of its SCR to 65 ng/J_I (0.15 lb/MMBtu), this facility would be capable of meeting the 200 ng/J_O (1.6 lb/MWh) output-based limit.

Second, the data base is adequate to evaluate the factors that can potentially affect SCR performance in a wide range of operating conditions. Fundamentally, like all post-combustion control devices, SCR is designed to respond to the characteristics of the stack gas. The primary difference between utility and non-utility boiler types may be that, on average, non-utility boilers may be more likely to operate with fluctuating loads. This difference in operating pattern may appear to have an impact on the characteristics of the stack gas. However, the NSPS is based on a 30-day averaging period to accommodate normal fluctuations in performance. Further, as discussed above, new analyses of two facilities that operate under cycling conditions have shown that SCR can meet the revised standard over a 30-day averaging period. The Birchwood facility reports daily cycle variations from 32 percent to 100 percent of load. The Logan facility's daily cycles ranged from 28 percent to 84 percent in the 3-month period for which data were supplied.

Another load-related technical issue raised is the difficulty in maintaining the temperatures necessary to minimize NO_X and HAP generation. In general, while designing an SCR system for a boiler, the boiler duty is taken into consideration. Specifically, the expected temperature range at the exit of the economizer is factored in the selection of an SCR catalyst formulation.

There are other steps that operators can take to ensure the desired SCR performance under variable or low load conditions. For example, if low load contributes to insufficient gas velocity to keep the flyash in suspension, the operator can add an ash hopper to divert the ash from the reactor and catalyst face. Alternatively, good ductwork system design can avoid these problems. Also, low boiler exit temperatures can be avoided by adding a economizer by-pass to keep the gas temperature higher at low loads. Finally, good flue gas mixing can overcome differences in gas flows and boiler firing conditions. Taking into consideration all of the above, in general, the EPA does not believe that SCR use is constrained by boiler duty.

Several commenters raised catalyst poisoning as an illustration that SCR is not suitable for all units. As a result of developments in catalyst technology, formulations are currently available that minimize the impact of poisoning. Nevertheless, the EPA believes this issue is really related to the cost of operating the SCR; appropriate catalyst management plans now make it possible to maximize catalyst life under plant operating conditions.

Another issue raised by commenters is that the SCR technology is immature and insufficiently demonstrated. The EPA disagrees with this comment. One recent study (Khan, S., *et al.*, ''SCR Applications: Addressing Coal Characteristic Concerns.'' Presented at the EPRI–DOE–EPA Combined Utility Air Pollutant Control Symposium, August 1997) identified at least 212 worldwide SCR installations on coal-fired units, which cover different types of boilers subjected to varying operating conditions and firing a variety of coals. Some of these installations were designed for and have achieved high NO_X reduction levels, exceeding 90 percent. Plants in Europe have been continuously using SCR for over 10 years. Finally, SCR-equipped units located in the U.S., such as the Logan, Birchwood, and Stanton facilities, are meeting some of the most stringent NO_X limits in the country.

2. Coal-related Issues

Several commenters expressed their concern that the proposed NSPS are not adequately demonstrated for all U.S. coals, particularly medium- and high-sulfur coals. They said that German and Japanese experience with these coals is undocumented, or, in the case of Japan, is with SCRs using hot-side electrostatic precipitators (ESPs) in a low-dust environment, compared to most U.S. boilers, which use cold-side ESP's in a high-dust environment. The commenters also rejected the Department of Energy Plant Crist high-sulfur coal demonstration project because of its limited scope.

The EPA disagrees that the use of SCR for high-sulfur coal applications is unsupported. In addition to one coal-fired plant in Japan and another in Austria firing coals with sulfur contents of 2.5 percent or higher, there are two coal-fired SCR installations in the U.S. that are firing coals with sulfur contents close to 2 percent. The Northampton generating facility, which is equipped with SNCR, successfully burns waste coal, and meets some of the most stringent NO_X limits in the U.S. (0.10 lb/MMBtu). In the Plant Crist demonstration project, the catalysts from various suppliers performed successfully. Criteria for successful performance at this demonstration included ammonia slip less than 5 ppm and SO_2 oxidation less than 0.75 percent.

In view of the experience both in the U.S. and abroad, the commenters' concerns over the use of SCR for high-sulfur coal applications is unsupported. In general for these installations, design features such as low ammonia slip, a catalyst that minimizes SO_3 conversion, and an economizer bypass to maintain proper flue gas temperatures at low loads are provided.

3. Selective Noncatalytic Reduction (SNCR)

Other commenters argued that SNCR was not adequately demonstrated on fluidized bed combustion boilers (FBCs) and/or large boilers. One commenter noted that the EPA's data showed that three of the five circulating FCBs that use SNCR stated that SNCR did not work properly when the units were operated at anything less than maximum capacity. Another commenter said SNCR ''has not been adequately demonstrated to work on large boilers (with a rated capacity greater than 390 MMBtu/hr), whether circulating bed or not.''

Flue gas temperatures exiting the furnace can range from 1,200 °C ± 110 °C (2,200 °F ± 200 °F) at full load down to 1,040 °C ± 70 °C (1,900 °F ± 125 °F) at half load. At similar loads, temperatures can increase by as much as 30 to 60 °C (50 to 110 °F) depending on the extent of ash deposition on heat transfer surfaces. Due to these variations in the temperatures, it is often necessary to inject the reagent at different locations or levels in the upper furnace or convective pass for effective NO_X reduction. A recent publication summarized the successful retrofit of retractable lances on a 100-megawatt coal-fired utility boiler equipped with SNCR, which greatly improved low load performance. Finally, the addition of hydrogen or other hydrocarbon reducing agent can be injected with the ammonia to lower the effective temperature range. Similarly, additives can increase the temperature range of urea application. By taking these sorts of steps, the EPA believes that operators can successfully operate SNCR, even under low load conditions.

Recent analysis of NO_X emissions data from a 110-megawatt, base-loaded, circulating fluidized-bed boiler equipped with SNCR (U.S. Generating Company's Northampton plant) indicates that the facility is quite capable of meeting the proposed standard. This facility achieves average input-based emissions of 38 ng/J_I (0.089 lb/MMBtu) and output-based emissions of less than 100 ng/J_O (0.8 lb/MWh), well below the output-based standard of 200 ng/J_O (1.6 lb/MWh) gross energy output.

Regarding SNCR on large boilers, the Acid Rain Phase II NO_X Response to Comments Document (p. 212) notes that SNCR has been demonstrated on coal-fired units as large as 1,230 MMBtu/hr (Germany) and on oil-fired units as large as 2,900 MMBtu/hr (Niagara Mohawk's Oswego Station). The SNCR application on Oswego shows that injectors can effectively penetrate the combustion gas flow in large boilers. Since the effectiveness of injecting SNCR reagent into large boiler casings has been proven, and SNCR has been applied to a variety of boilers, the EPA does not see boiler size as a restriction for applying SNCR to NSPS sources.

B. Regulatory Approach

1. Fuel Neutral Approach

Several commenters supported a cap on NO_X emissions at the same level for nearly all fuel types, because it allows fuel switching as a control technology and is an ''important and positive step toward cleaner air . . . across the nation.'' Commenters stated that currently, natural gas-fired units are subject to the most stringent standard while coal and residual oil are allowed to emit much larger quantities of NO_X. The proposed rule will remove any disincentive toward natural gas that has been created by this situation. One commenter wrote that a fuel neutral standard would not penalize any particular industry, but would encourage competition for new efficient boilers and cogeneration units, and would be consistent with the EPA's emphasis on pollution prevention.

Other commenters opposed the same NO_X emission limit for all fuel types arguing that it sets a lower than lowest achievable emission rate (LAER) and best available control technology (BACT) level for coal-fired boilers, while significantly relaxing standards for natural gas units by a factor of two to four times. Another commenter stated that a number of gas- and oil-fired units in the U.S. currently achieve approximately one-tenth of the proposed limit with the application of SCR.

Commenters stated that the ''proposal violates the Act by providing an overwhelming incentive for new and modified electric generating units to burn natural gas to the exclusion of coal.'' Other commenters opposed the fuel neutral approach because of fuel availability and cost factors. One commenter stated that natural gas is not uniformly distributed and evenly available to all industrial users. The commenter asserted that the proposed emission limit ''favors industrial development in regions that have an ample supply of natural gas and penalizes regions that have no practical option for steam production at industrial facilities other than coal.''

One commenter said the fuel neutral emission rate may inadvertently be a dis-benefit to the introduction of low NO_X technology. The commenter postulated that ''the result then might be continued operation of older more polluting sources than might otherwise occur.''

The EPA disagrees with the commenters who contend that the fuel neutral format creates an overwhelming or disproportionate incentive to use fuels other than coal. The EPA's approach is designed to allow the continued use of coal as a fuel in those cases where it is desirable. The standard would, however, also not discourage conversion to natural gas where it makes sense in the individual application.

The EPA believes the fuel neutral approach will expand the control options available by allowing the use of clean fuels as a method for reducing NO_X emissions. Since projected new utility steam generating units are predominantly coal-fired, the use of clean fuels (i.e., natural gas) as a method of reducing NO_X emissions from these coal-fired steam generating units may give the regulated community a more cost-effective option than the application of SCR for meeting the NO_X limit. Similarly, for industrial units, the use of clean fuels as a method of reducing emissions may be a cost-effective approach for coal-fired and residual oil-fired industrial steam generating units.

The fuel neutral approach also fits well with section 101(a)(3) of the Act's emphasis on pollution prevention, which is one of the EPA's highest priorities. Because natural gas is essentially free of sulfur and nitrogen and without inorganic matter typically present in coal and oil, SO_2, NO_X, inorganic particulate, and air toxic compound emissions can be dramatically reduced, depending on the degree of natural gas use. With these environmental advantages, gas-based control techniques should be viewed as a sound alternative to flue gas treatment technologies for coal or oil burning.

Finally, the proposed amendments do not relax the existing NSPS for natural gas units. In fact, the 65 ng/J_I (0.15 lb/MMBtu) heat input reflects a 50- and 25-percent reduction in NO_X emissions over the current subpart Da limits for oil-fired and gas-fired units, respectively. Revised subpart Db would not require any additional controls for new gas-fired and distillate oil-fired units over the current NSPS because of the costs associated with additional controls. However, subpart Db does not relax the existing standards for these units either.

2. Output-Based Format to Subpart Da

Several commenters supported the output-based format of the proposed subpart Da standard, because they felt it would reward energy-efficient generators. However, other commenters opposed the format for the following reasons:

(1) The incentives to be efficient have recently increased due to the newly competitive nature of the industry, and will continue to increase without output-based standards.

(2) The format would add significant burdens to an already complicated monitoring system for utilities.

(3) There are inconsistencies between the proposed NSPS output-based format and several other input-based regulations that are also applicable to these sources.

(4) NO_X averaging of NSPS units with existing units would be very complicated.

(5) The output-based format is inappropriate and inaccurate for cogeneration facilities that produce steam in addition to or in place of electric generation. Because the customers dictate the temperature and pressure conditions of the steam that is produced, the generator has no choice and must produce the desired product. In addition, the EPA method of equating steam production to electric production was over-simplified and punitive in that it does not consider all of the potential steam production conditions, and it would increase the cost of efficient cogeneration.

(6) An output-based NSPS does not promote energy efficiency because it ''makes no allowance for the use of low Btu fuels (such as waste coal) that would otherwise go unused,'' which would increase the costs of electrical generation and discourage national energy self-sufficiency. Further, the proposed NSPS is inconsistent with recent utility deregulation, because ''an important goal of recent utility de-regulation was to allow market forces to minimize the cost of electric power to consumers, without eroding environmental protection.''

The EPA continues to believe in the benefits associated with an output-based standard for new sources that encourages energy efficiency. As discussed in section III.C, however, the EPA has revised the final standard for existing sources that become subject to the NSPS because of modification or reconstruction, to be in the equivalent input-based format of 65 ng/J_I (0.15 lb/MMBtu).

The changes in the output-based format, discussed below in section III.B.3, will simplify the compliance demonstration for sources by eliminating the need to convert input values to output values. Given that the output-based format is a new regulatory approach for these sources, it is inevitable that some inconsistencies in monitoring requirements associated with various programs to which individual sources might be subject would occur. While the EPA is concerned about these apparent inconsistencies, the EPA also feels that the requirements of the NSPS stand on their own merits. The NSPS provisions do not require any new monitoring at sources that is not already required by some other program (i.e., the Acid Rain program.) However, in some instances, the Title V permit process and activities such as permit streamlining may provide relief to sources on a case-by-case basis. In addition, the EPA will continue to explore additional ways to provide monitoring relief that do not compromise the ability of EPA to adequately enforce Federal standards.

As discussed below in section III.B.3, the EPA did examine possible revisions to the steam credit allowance for cogeneration facilities. These issues are further addressed in that section.

Finally, the EPA believes that low-cost fuels can be used effectively at facilities subject to the final standards. As discussed, the U.S. Generating

Company's Northampton facility is currently performing better than would be required under the amended NSPS and uses waste coal as its sole energy source.

3. Input to Output Conversion Assumptions

The EPA revised the approach used to develop the output-based limit based on analysis of comments submitted on the input to output conversion assumptions relied on in developing the proposed standard. As discussed in detail in this section, the EPA will finalize the standard for new sources at a level of 200 ng/J_O (1.6 lb/MWh) gross energy output. The revised standard contained in this final rule is based on actual measured energy output, rather than measured heat input converted to energy output, as was the case with the proposed standard. This change addresses concerns related to overall heat rates, steam credits for cogeneration facilities, and gross versus net output. The key underlying assumption inherent in the selection of the level of the final standards at 200 ng/J_O (1.6 lb/MWh) gross output, i.e., the input-based standard of 65 ng/J_I (0.15 lb/MMBtu), is maintained.

38-Percent Baseline Efficiency. There were comments both in support of and opposed to the selection of an average 38-percent baseline boiler efficiency. The selection of a baseline efficiency value is intimately tied to the selection of a corresponding heat rate. Based on data available since the proposed standards, the Agency has been able to evaluate heat rate directly.

9,000 Btu/kWh Heat Rate. The majority of commenters opposed the selection of an assumed 9,000 Btu/kWh heat rate for use in converting input-derived NO_X emissions to an output basis. Several commenters provided examples of units that operate in the 10,000 to 11,000 Btu/kWh range. The commenters indicated that net heat rates of 10,000 to 10,500 Btu/kWh are typical of state-of-the-art units.

In light of additional data supplied by commenters and collected by EPA, the EPA has decided to revise the assumed heat rate. First, as explained later, the output-based standard is now based on gross output instead of net output, so the following discussion will be in terms of gross heat rates.

The EPA collected data from four additional utility boilers that are considered to be new and state-of-the-art from an emissions standpoint. The first boiler is a base-loaded, fluidized bed combustion cogeneration unit that fires waste coal and is equipped with SNCR (Northampton). This unit's average gross heat rate (with 50 percent credit for export steam) is less than 9,000 Btu/kWh. The second unit is a pulverized coal-fired, cogeneration unit that operates under cycling load and is equipped with SCR (Logan). This unit's average gross heat rate (with 50 percent credit for export steam) is approximately 10,250 Btu/kWh. The third utility boiler (Stanton) has an average heat rate of 10,250 Btu/kWh. The Birchwood cogeneration unit, the fourth facility, reported that they cycle between heat rates of approximately 10,700 Btu/kWh at 32 percent load and 9,000 Btu/kWh at 100 percent load. The heat rates reported by the Birchwood cogeneration unit are based on a 100 percent credit for export steam.

The EPA conducted statistical analyses in which the objective was to assess long-term NO_X emission levels, on an output basis, that can be achieved continuously. Statistically, Logan, Northampton, and Birchwood all can meet the revised output-based standard of 200 ng/J_O (1.6 lb/MWh) (gross) on a 30-day rolling average.

Cogeneration Steam Credit. Several commenters asserted that using only 50 percent of the thermal energy from the steam generated at cogeneration facilities in calculations of output-based emission rates is inappropriate. The commenters reported that the 50-percent allocation is from a section of the Public Utility Restructuring Policy Act (PURPA) in which the 50-percent thermal output is used as part of a definition of a PURPA-qualifying facility. Basing the NSPS on this factor is not justified according to the commenters. The commenters also suggested a variety of ways to calculate the steam credit including (1) converting the electric output to MMBtu plus the enthalpy of the full steam or hot water output in MMBtu, or the electric output in MWh_{el} plus the enthalpy of the full steam or hot water output in MWh_{th}, (2) measuring pounds of NO_X per million Btu of steam produced at the boiler steam header, or (3) measuring the electric output plus the full thermal output in consistent units. Another commenter suggested that since each application would differ in efficiency, credit should be given for the heat actually used and calculated on a case-by-case basis.

Other commenters insisted that efficiency should not be used as a compliance measure. The commenter explained that the efficiency calculation is an extra, unneeded step. The commenters reported that all that is needed is a CEMS to directly measure NO_X and an electric or thermal measurement for output in units of MMBtu or MWh.

As discussed, the EPA has revised the form of the final standards to be based on a direct measure of output, i.e., mass of NO_X per unit of gross energy output. In order to evaluate the data supporting the level of the standard, the EPA had to conduct data analysis to address the level of steam credit for cogeneration facilities. The EPA considered three approaches for addressing the issue of steam credit for cogeneration facilities: (1) Allow credit for steam as if it were being converted into electricity; (2) Allow credit in the form of 50 percent of the thermal value (enthalpy) of the steam; and (3) Allow credit for greater than 50 percent of the value of the steam, up to 100 percent.

The EPA decided not to allow credit for steam as if it were being converted into electricity because the EPA wants to encourage cogeneration. Allowing credit as if electricity would only provide credit for up to 38 percent of the value of the steam, which is the reported maximum of the efficiency of steam to electricity conversion.

The EPA also decided not to allow for greater than 50-percent credit for the steam. Based on analysis of heat rates for cogeneration facilities, the EPA has determined that once a facility exceeds 50 percent and approaches 100 percent credit for the steam, there is a potential for calculating an artificially high output rate, particularly if much of the steam is exported. As another option, the EPA considered allowing 100 percent credit for steam, but capping the amount of steam for which credit could be received to a certain percentage of total output. This approach was deemed to be too complex from a monitoring standpoint.

Therefore, the EPA retained the proposed 50-percent credit for export steam from cogeneration facilities on the basis that it encourages cogeneration, will not result in artificially high output rates, and will not require complex monitoring. This outcome is based on the information available to the Agency at this time. We recognize, however, that cogeneration increases the efficiency of power generation and, as discussed above, comments received during the rulemaking process indicate that there may be alternative ways of calculating the value of thermal output that warrant further consideration. We are interested in exploring alternative approaches to cogeneration and request further comment on this issue. We particularly are interested in hearing about alternatives that would allow us to determine the fraction of the energy delivered to the industrial process that

is actually used and should, therefore, be included in the calculation of the gross output from cogeneration facilities.

Gross Versus Net Output. While some commenters support the use of a net output basis to the final format of the standard because it encourages energy efficiency at the facility, several other commenters raised concerns regarding how net output would actually be measured in the industry. One commenter reported that the output-based format would ''require significant and costly changes to the software of monitoring and reporting systems.'' Other commenters reported that electrical output cannot be measured directly because it is dependent on the ''electrical usage by hundreds of motors and other auxiliary equipment located throughout the plants.'' They claimed that net generation cannot be measured ''by simply installing a wattmeter.''

One commenter recommended basing the standards on gross rather than net output to account for the power drain associated with many types of control technologies. Other commenters protested that the proposal did not include a specific methodology for determining the unit net output. They said the EPA did not provide for a subsequent comment period on a ''significant component'' of the proposal, and the EPA should withdraw the proposal until a complete and thorough package can be provided for full public review and comment.

The EPA has reconsidered its position, and has decided to finalize the rule based on the use of gross output because of the monitoring difficulties inherent in the net output methodology. In particular, measuring net output at facilities with both affected and nonaffected units could be problematic, because a single meter on the electricity leaving the facility could not effectively allocate the electricity leaving the affected boiler. The EPA may revisit this issue should EPA develop a methodology to determine the net heat output in all circumstances.

C. Modification and Reconstruction

Commenters expressed opposition to the applicability of the NSPS to modified units. They said that Congress' intent in developing the NSPS program was to limit applicability to sources that could be designed to include state-of-the-art pollution control technology, and that the emphasis on new sources reflected Congress' recognition of the difficulty and expense of retrofitting control technology on existing sources.

One commenter said that the EPA was ''acting unlawfully by failing to consider the costs that will be incurred by existing sources that become the subject of the proposed NO_X standard.'' The commenter proffered that existing coal-fired sources are likely to become subject to this rule eventually, unless they are specifically excluded. According to this commenter, if this occurs, the existing sources will be faced with excessive retrofit costs in order to attain the standard.

One commenter stated that ''the installation of SCR on existing units * * * would be economically infeasible.'' A possible solution proposed by a commenter was that the EPA propose a standard that modified units could meet without SCR, or justify the use of the same standards as for new units. One commenter reasoned that ''since EPA states that few modified sources will be affected, adding specific language clarifying that such units are not subject to the NSPS would raise few, if any, policy implications.'' Another possible solution presented was that the EPA specifically exclude modified boilers from the final NSPS.

One commenter stated that the proposed NO_X emission limit was not demonstrated for non-gas-fired modified sources and that the new limit should not apply to sources that come under the NSPS through modification. In situations where liquid or solid fuel is fired, it is not always possible or reasonable to comply with the proposed limit. For instance, the commenter has a residual oil-fired boiler that could not be retrofitted to meet the proposed standard, and add-on controls would not be feasible because of limited space and unreasonable cost.

One commenter said EPA is aggressively pursuing businesses that have made efficiency improvements to force the units to meet NSPS under the modification provisions in 40 CFR part 60. The commenter stated that the EPA ''clearly has the discretion and duty to distinguish between new and existing sources which become subject to this rule.''

The Clean Air Act defines a modification as ''any physical change in, or change in the method of operation of, a stationary source which increases the amount of any air pollutant emitted by such source or which results in the emission of any air pollutant not previously emitted.'' (Section 111(a)(4)) Section 60.14 of the subpart A General Provisions provides additional guidance on EPA's interpretation of this definition, and specifically excludes changes in ownership of an existing facility from being considered a modification. (40 CFR 60.14) In addition, a key aspect to the definition of modification is that the change to the facility must result in an emissions increase.

Section 111(b)(1)(B) of the Act requires the Administrator to promulgate standards of performance for ''new sources'' in each category of sources which in the Administrator's judgment causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare. Section 111(a)(2) of the Act defines ''new source'' to include stationary sources which are modified after an applicable standard of performance is proposed. The EPA finds nothing in the comments that would justify ignoring this clear statutory mandate. In developing standards of performance, section 111(a)(1) of the Act does, however, allow the Administrator to take into consideration the cost of achieving the required reduction and any nonair quality health and environmental impact and energy requirements. As noted at proposal, the efficiency of most existing electric utility steam generating plants ranges from 24- to 38-percent efficient. The EPA selected 38-percent efficiency as the baseline reflective of NSPS units. The EPA believes that selecting the 38-percent efficiency level for new electric utility steam generating units was an appropriate exercise of its discretion based on the available information. The EPA realizes, however, that existing units are likely to operate in the lower end of this range, with higher associated heat rates, which would make it more difficult to meet an output-based standard. These sources would have to compensate with higher control device performance (up to a 40-percent increase in performance), which would be more costly. To ease this potential burden, the EPA has decided to allow any existing units that become subject to the NSPS as a result of undergoing a modification or reconstruction to meet the equivalent input-based standard of 65 ng/J_I (0.15 lb/MMBtu) on which the output-based standard applicable to new units is based. This change will eliminate the concern that higher average heat rates at existing units could adversely affect a source's ability to meet an output-based standard. This level of control represents the same overall level of SCR performance that would be required of new units, but lacks the benefits attributed to promoting energy efficiency that the output-based format provides.

D. Applicability and Exemptions

1. Gas Turbines

Commenters stated that the EPA should not apply the proposed standard to modified and reconstructed waste heat boilers. The commenters said these waste heat systems are typically installed in the ductwork of a gas turbine exhaust and are not amenable to significant modification for NO_X control because of their configuration. According to the commenters, tubes are tightly packed, space for reconfiguration is extremely limited, and possible back pressure impacts on the upstream device are a major concern. Applying the NSPS would require the combined system to meet the new standard, because the NO_X from the upstream device (i.e., combustion turbine) cannot be separated from the steam generator NO_X for purposes of add-on control. The commenters said that add-on controls are not demonstrated for such systems.

The systems described by the commenters would be subject to subpart GG of this part, standards of performance for stationary gas turbines, and subparts Da or Db. Because these standards cover separate emission sources, continued applicability of subparts Da or Db is needed. However, the EPA's ongoing Industrial Combustion Coordinated Rulemaking (ICCR) could result in the EPA extending the applicability of subpart GG to the duct burner, which is currently covered by subparts Da and Db. The EPA agrees that if this were to occur, the ICCR-driven revisions to subpart GG would pose a potential conflict with the subparts Da and Db. Therefore, the EPA will revise subparts Da and Db to exempt sources that may also become subject to subpart GG, should such revisions to subpart GG occur.

2. Ten-Percent Exemption

Commenters noted that the proposed revision appears to apply to all steam generating units, including units that are excluded from the current standard because they fire 10 percent or less fossil fuel. The commenters did not believe that the EPA intended that the revised NO_X limit should apply to facilities that combust a limited amount of fossil fuel. Several commenters suggested clarifying the following language at the end of § 60.44b(l)(1): ''* * * 86 ng/J_I (0.20 lb/MMBtu) heat input unless the affected facility has an annual capacity factor for coal, oil, and natural gas of 10 percent (0.10) or less and is subject to a federally enforceable requirement that limits operation of the facility to an annual capacity factor of 10 percent (0.10) or less for coal, oil, and natural gas; or * * *.''

The EPA did not intend to remove the 10-percent exemption from the revised NSPS. The EPA will add the suggested regulatory language to clarify that this exemption still applies.

3. Municipal Waste Combustors

Commenters pointed out that, as written, the proposed NO_X revisions would include municipal solid waste combustors (MWC) that only use a limited amount of fossil fuels for startup purposes and supplemental fuel during those periods when the heat content of the waste is low, in order to maintain good combustion conditions. These units are already subject to subpart Eb of this part, the revised NSPS for large MWC. The commenters suggested that the addition of the 10-percent exemption, discussed above, would alleviate this concern or that exemptions for MWC units subject to the relevant MWC rules would make sense.

As discussed above, the EPA has included the language regarding the 10-percent exemption to the final rule, which should cover these types of sources. In addition the EPA will revise the final rule to exempt units that are subject to subpart Eb to avoid any possible conflicts.

E. Monitoring

Several commenters requested that the EPA clarify and expand the allowance of the use of part 75 CEMS in place of the subparts Da and Db required monitoring provisions. In particular, commenters requested that part 75 elements such as data validation procedures, CEMS configuration specifications, and methods of compliance determination should be deemed to satisfy subparts Da and Db monitoring provisions.

In the past, the EPA determined that Acid Rain CEMS can be used as NSPS Subpart Da CEMS. That determination is available on the Office of Enforcement and Compliance Assurances's web site. A subpart Db boiler equipped with an acid rain CEMS can also use this CEMS as a subpart Db CEMS. In either case, the reports generated by this CEMS must be generated according to the provisions of subparts Da or Db, as applicable, and submitted to the authority in charge of the NSPS program, because the NSPS and acid rain programs have different requirements and are managed by different authorities.

Regarding data validation procedures, the EPA headquarters already maintains the acid rain data base and the AIRS data base, which is suitable for reports from non-acid rain programs. In addition, several States maintain their own data bases. The EPA believes that the data validation issue should not lead to any conflicts considering that the acid rain and the subparts Da and Db report formats must follow their own requirements. The EPA headquarters has addressed a few span-related issues upon request and will continue this practice under the part 60 General Provisions. Finally, emission limits during hours of invalid data must be met using other means than CEMS data according to the requirements of § 60.47a(f) or § 60.48b(f), as applicable.

The EPA has added language to § 60.47a(c) to clarify that ''If the owner or operator has installed a nitrogen oxides emission rate continuous emission monitoring system (CEMS) to meet the requirements of part 75 of this chapter and is continuing to meet the ongoing requirements of part 75 of this chapter, that CEMS may be used to meet the requirements of this section, except that the owner or operator shall also meet the requirements of § 60.49a. Data reported to meet the requirements of § 60.49a shall not include data substituted using the missing data procedures in subpart D of part 75 of this chapter, nor shall the data have been bias adjusted according to the procedures of part 75 of this chapter. Similar language has also been added to § 60.48b(b) to clarify the use of part 75 CEMS with subpart Db affected facilities.

IV. Administrative Requirements

A. Docket

This final rulemaking action is subject to section 307(d) of the Act. Accordingly, the EPA has established a docket (No. A–91–71), which consists of an organized and complete file of all information submitted to, or otherwise considered by, the EPA in the development of this action. The docket includes all memoranda and studies cited by the EPA in this preamble. The principal purposes of the docket are: (1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the rulemaking process, and (2) to serve as the record in case of judicial review. The docket is available for public inspection at EPA's Air Docket, which is listed under the **ADDRESSES** section of this document.

B. Office of Management and Budget (OMB) Review

1. Paperwork Reduction Act

These revisions contain no changes to the information collection requirements of the current NSPS that would increase the burden to sources, and the currently approved Office of Management and Budget (OMB) information collection requests are still in force for the amended rules. These information collection requests are identified as number 1053.05, OMB 2060–0023, for 40 CFR 60.40a–49a and number 1088.08, OMB 2060–0072 for 40 CFR 60.40b-49b. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Some changes in the rule, such as allowing the submittal of electronic reports, are provided as an option to sources, and should reduce burden to those sources electing to use this report format. Other rule changes, such as the difference in numerical NO_X emission limits and the output-based format of the standard, do not result in additional recordkeeping and reporting requirements, beyond those already required by other programs such as the Acid Rain requirements in part 75.

2. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1994), the Agency must determine whether the regulatory action is ''significant'' and, therefore, subject to OMB review and the requirements of the Executive Order. The Order defines ''significant'' regulatory action as one that is likely to lead to a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligation of recipients thereof; (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, the EPA has determined that this rule is a ''significant regulatory action'' because this action may have an annual effect on the economy of $100 million or more and it raises novel policy issues, such as the output-based format of the subpart Da emission limit for new sources and the fuel neutral approach to the emission limits under both subparts. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

C. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''UMRA''), signed into law on March 22, 1995, the EPA must prepare a statement to accompany any proposed rule where the estimated costs to State, local, or tribal governments, or to the private sector, will be $100 million or more in any one year. Under section 205, the EPA must select the most cost-effective, least costly, or least burdensome alternative that achieves the objective of the rule and is consistent with statutory requirements. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly impacted by the rule.

The unfunded mandates statement under section 202 must include: (1) A citation of the statutory authority under which the rule is proposed; (2) an assessment of the costs and benefits of the rule, including the effect of the mandate on health, safety and the environment, and the federal resources available to defray the costs; (3) where feasible, estimates of future compliance costs and disproportionate impacts upon particular geographic or social segments of the nation or industry; (4) where relevant, an estimate of the effect on the national economy; and, (5) a description of the EPA's prior consultation with State, local, and tribal officials.

Since this final rule is estimated to impose costs to the private sector in excess of $100 million, the EPA has prepared the following statement with respect to these impacts.

1. Statutory Authority

The statutory authority for this rulemaking is identified and described in section I.A of the preamble. As required by section 205 of the UMRA, and as described more fully in the proposal preamble (62 FR 36948, section III) and section III of this preamble, the EPA has chosen to promulgate a rule that is the least burdensome alternative for regulation of these sources that meets the statutory requirements under the Act.

2. Costs and Benefits

As described in section VI of the proposal preamble, the estimate of annual social cost for the regulation is $40 million for utility boilers and $41 million for industrial boilers in the year 2000. Certain simplifying assumptions, such as no fuel switching in response to the rule, may have resulted in a significant overestimation of these costs.

The pollution control costs will not impose direct costs for State, local, and tribal governments. Indirectly, these entities face increased costs in the form of higher prices for electricity and the goods produced in the facilities requiring new industrial boilers that would be subject to this final rule. There are no federal funds available to assist State, local, or tribal governments with these indirect costs.

Because this regulation affects boilers as they are constructed (or modified), the emission reductions attributable to the regulation increase year by year until all existing boilers have been replaced. In the year 2000, the NO_X emission reduction relative to the baseline for utility boilers is estimated to be 26,000 tons per year. In the year 2000, the NO_X emission reduction relative to the baseline for industrial boilers that represent net additions to existing capacity is estimated to be 20,000 tons per year. Emissions reductions from replacement boilers are not quantified because of difficulties in characterizing emission rates for the boilers being replaced and the inability of the replacement model to predict selection of different types of boilers in both the baseline case and in response to the regulation. A qualitative analysis of industrial boiler replacement raises the possibility that replacement delay due to the revision may keep some boilers continuing to emit at a higher level than they would in the baseline case where they would be replaced by a lower emitting boiler.

Reducing emissions of NO_X has the potential to benefit society in a number of ways. Emissions of NO_X result in a wide range of damages, ranging from human health effects to impacts on ecosystems. They not only contribute to ambient levels of potentially harmful nitrogen compounds, but they also have important precursor effects. In combination with volatile organic compounds (VOCs), they contribute to the formation of ground level ozone. Along with emissions of sulfur oxides, they are also precursors to particulate matter and acidic deposition.

See Table 2 for a summary of linkages between NO_X emissions and damage categories.

TABLE 2.—LINKAGES BETWEEN NO_X EMISSIONS AND DAMAGE CATEGORIES: STRENGTH OF THE EVIDENCE

	Direct effects	Precursor effects		
	Ambient NO_X levels	Ambient ozone levels	Ambient particulate matter	Acid deposition
Human Health:				
Acute Morbidity	√√√	√√√	√√√	√
Chronic Morbidity	√√	√	√√√	
Mortality	.....	√	√√√	.....
Ecosystems:				
Terrestrial	√√ [1]	√√	√√	.....
Aquatic	√√	.....	.....	√√√
Commercial Biological Systems [2]:				
Agriculture	√	√√√	.....	.....
Forestry	.....	√√	.....	√
Visibility	√√	.....	√√√	.....
Materials	√√√	.....	√√√	.....

√ = weak evidence.
√√ = limited evidence.
√√√ = strong evidence.
[1] Evidence indicates that NO_X can have both positive and negative effects in this category.
[2] Evidence for this category relates specifically to certain commercial crop or tree types rather than to the more general terrestrial damages that are covered in the separate ecosystems category.

Benefits are only qualitatively addressed in the regulatory impacts analysis (RIA) because of difficulties in physically locating the not yet built boilers and translating their emission reductions into changes in ambient concentrations of nitrogen compounds, ozone concentrations, and particulate matter concentrations.

3. Future and Disproportionate Costs

The rule is not expected to have any disproportionate budgetary effects on any particular region of the nation, any State, local, or tribal government, or urban or rural or other type of community. Only very small increases in electricity prices are estimated. See section VIII C.4 of the proposal preamble for more detail.

4. Effects on National Economy

Significant effects on the national economy from this rule are not anticipated. See section VIII.C.4 of the proposal preamble for more detail.

5. Consultation with Government Officials

The UMRA requires that EPA describe the extent of the Agency's prior consultation with affected State, local, and tribal officials, summarize the officials' comments or concerns, and summarize the EPA's response to those comments or concerns. In addition, section 203 of the Act requires that the EPA develop a plan for informing and advising small governments that may be significantly or uniquely impacted by a proposal.

In the development of this rule, the EPA has provided small governments (State, local, and tribal) the opportunity to comment on this regulatory program. A fact sheet which summarized the regulatory program, the control options being considered, preliminary revisions, and the projected impacts was forwarded to seven trade associations representing State, local, and tribal governments. A meeting was held for interested parties to discuss and provide comments on the program. Written comments also were requested. The main comments received dealt with the need to consider the impacts of the revisions on small units and facilities. Commenters also stated that the requirement for an integrated resource plan is unnecessary and burdensome for small operators and may constitute an unfunded mandate. In response to this concern, the EPA removed the requirement for an integrated resource plan from this rulemaking. In response to the concern regarding the cost impacts on small industrial steam generating units, the EPA proposed a higher NO_X emission limit for industrial units than it proposed for utility units. The revised limit for industrial units effectively results in no additional controls for gas and distillate oil-fired industrial units over that required to comply with the current emission limits. As described in sections VIII.D.3 and D.4.c of the proposal preamble, the impacts on small businesses and governments have been analyzed and indicate that small governments are not significantly impacted by this rule and thus no plan is required. Public comments received from government entities were largely limited to technical comments on the proposed revisions. However, the City of Tampa, Florida, did raise a burden-related issue due to concerns regarding the potential overlap in applicability between subpart Db and other NSPS provisions affecting municipal waste combustors. As described in section III.D.3, the EPA has addressed their concerns by reinstating the 10-percent exemption and by specifically exempting MWC units from applicability to subpart Db.

D. Executive Order 12875

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

The EPA has concluded that this rule may create a mandate on State, local, and/or tribal governments and that the Federal government will not provide the funds necessary to pay the direct costs incurred by the State, local and/or tribal governments in complying with the mandate. These governments will also have the responsibility to carry out the

rule by incorporating it into permits and enforcing it, as delegated. They will collect permit fees that pay for the costs of applying the rule.

In developing this rule, EPA consulted with these governments to enable them to provide meaningful and timely input in the development of this rule. As discussed in section IV.C.5 of this preamble, EPA provided numerous opportunities for these stakeholders to comment on the proposed amendments and has carefully considered their input.

As described in sections IV.C.2 and IV.C.3, EPA does not expect this rule to impose direct compliance costs on State, local, and tribal governments. At most, these entities will face increased indirect costs in the form of slightly higher prices for electricity and the goods produced in facilities requiring new industrial boilers that would be subject to this final rule. Compared to the estimated health and environmental benefits, described in section IV.C.2 of this preamble, EPA believes the need to issue this final rule outweighs the potential costs to these governmental entities.

E. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. The EPA received extensive public comments on the proposed amendments. None of the commenters raised any issues of direct significance to Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

F. Regulatory Flexibility Act

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this rule will not have a significant economic impact on a substantial number of small entities. The Regulatory Flexibility Act (RFA) requires EPA to give special consideration to the impact of regulation on small businesses, small organizations, and small governmental units. The major purpose of the RFA is to keep paperwork and regulatory requirements from getting out of proportion to the scale of the entities being regulated, without compromising the objectives of, in this case, the Clean Air Act. The RFA specifies that the EPA must prepare an initial regulatory flexibility analysis if a proposed regulation will have a significant economic impact on a substantial number of small entities.

Firms in the electric services industry (SIC 4911) are classified as small by the U.S. Small Business Administration if the firm produces less than four million megawatts a year. For the time period of the analysis (1996 to 2000), one projected new utility boiler may be affected and small. Of the 13 projected new utility boilers, 10 are known to not be small, and 2 of the remaining 3 are not expected to incur additional control costs due to the regulation. The size of the owning entity is unknown for the remaining utility boiler. That boiler also has the smallest cost in mills/kWh (0.07) of the 11 projected units to have additional control costs. Therefore, no significant small business impacts are anticipated for the utility boilers.

Regarding industrial boilers, EPA expects that some small businesses may face additional pollution control costs. It is difficult to project the number of industrial steam generating units that will both incur control costs under the regulation and be owned by a small entity. Since the rule only affects new sources, and plans for new industrial boilers are not available (as they are for electric utilities), linking new projected boilers to size of owning entity is difficult. The projection of 381 new boilers has 293 of the boilers incurring no costs because they are projected to be either gas-fired or distillate-oil-fired units that would require no additional control. Some of the 88 remaining boilers which are projected to incur costs in complying with the regulation may be owned by small entities. The size of the owning entity and the size of the boiler are not related in any simple way, but smaller entities may be more likely to have a smaller boiler. The applicability size cut off of 100 million Btu/hour heat input for industrial boilers would be expected to result in fewer small entities being affected. Since only 88 industrial boilers are expected to incur any costs and many of them are likely to be owned by large entities, the EPA projects that fewer than 88 of these boilers will be owned by small entities.

The information used for economic impact analysis for the proposed rule matches boiler size and fuel type to various industries. These data overestimate the share of boilers that are residual-oil-fired and coal-fired, but the data are nonetheless useful for estimating the potential economic impact of the rule on small entities in terms of cost-to-sales ratio. This analysis estimates costs as a percent of value of shipments (closely related to sales) for affected facilities. The average control cost as a percentage of value of shipments for all affected facilities is 0.07 percent. The range of average control cost across industries varies from a low of 0.004 percent for primary metals to a high of 0.8 percent for the paper industry. Although the cost varies by industry, boiler size, and fuel, it is unlikely that any affected small entities will have a control cost to sales ratio of greater than one percent.

G. Executive Order 13045

Executive Order 13045 applies to any rule that EPA determines (1) economically significant as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) directs all Federal

agencies to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test methods, sampling and analytical procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American Society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive Engineers (SAE). The NTTAA requires Federal agencies like EPA to provide Congress, through OMB, with explanations when an agency decides not to use available and applicable voluntary consensus standards.

This action does not involve any new technical standards or the incorporation by reference of existing technical standards. Therefore, consideration of voluntary consensus standards is not relevant to this action.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2).

J. Clean Air Act Procedural Requirements

1. Administrator's Listing—Section 111

As prescribed by section 111(b)(1)(A) of the Act, establishment of standards of performance for electric utility steam generating units and industrial-commercial-institutional steam generating units was preceded by the Administrator's determination that these sources contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare.

2. Periodic Review—Section 111

This regulation will be reviewed again 8 years from the date of promulgation of these revisions to the standard. The review will include an assessment of the need for integration with other programs, enforceability, improvements in emission control technology, and reporting requirements.

3. External Participation—Section 117

In accordance with section 117 of the Act, publication of this review was preceded by consultation with independent experts. The Administrator has considered comments on several aspects of the proposed revisions, including economic and technical issues.

4. Economic Impact Analysis—Section 317

Section 317 of the Act requires the EPA to prepare an economic impact assessment for any emission standards under section 111 of the Act. An economic impact assessment was prepared for the proposed revision to the standards. In the manner described above under the discussions of the impacts of, and rationale for, the proposed revision to the standards, the EPA considered all aspects of the assessments in promulgating the revision to the standards. The economic impact assessment is included in the docket listed at the beginning of this document under **SUPPLEMENTARY INFORMATION.**

Statutory Authority

The statutory authority for this rule is provided by sections 101, 111, 114, 301, and 407 of the Clean Air Act, as Amended; 42 U.S.C. 7401, 7411, 7414, 7601, and 7651f.

List of Subjects in 40 CFR Part 60

Environmental protection, Air pollution control, Electric utility steam generating units, Industrial-commercial-institutional steam generating units, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: September 3, 1998

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter 1 of the Code of Federal Regulations is amended as follows.

PART 60—[AMENDED]

1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401, 7411, 7413, 7414, 7416, 7601, and 7602.

Subpart Da—[Amended]

2. Section 60.40a is amended by revising paragraph (b) to read as follows:

§ 60.40a Applicability and designation of affected facility.

* * * * *

(b) Unless and until subpart GG of this part extends the applicability of subpart GG of this part to electric utility steam generators, this subpart applies to electric utility combined cycle gas turbines that are capable of combusting more than 73 megawatts (250 million Btu/hour) heat input of fossil fuel in the steam generator. Only emissions resulting from combustion of fuels in the steam generating unit are subject to this subpart.

(The gas turbine emissions are subject to subpart GG of this part.)

* * * * *

3. Section 60.41a is amended by adding a definition for ''Gross output'' in alphabetical order to read as follows:

§ 60.41a Definitions.

* * * * *

Gross output means the gross useful work performed by the steam generated. For units generating only electricity, the gross useful work performed is the gross electrical output from the turbine/generator set. For cogeneration units, the gross useful work performed is the gross electrical output plus one half the useful thermal output (i.e., steam delivered to an industrial process).

* * * * *

4. Section 60.44a is amended by revising paragraphs (a) introductory text and (c) introductory text and by adding paragraph (d) to read as follows:

§ 60.44a Standard for nitrogen oxides.

(a) On and after the date on which the initial performance test required to be conducted under § 60.8 is completed, no owner or operator subject to the provisions of this subpart shall cause to be discharged into the atmosphere from any affected facility, except as provided under paragraphs (b) and (d) of this section, any gases which contain nitrogen oxides (expressed as NO_2) in excess of the following emission limits, based on a 30-day rolling average:

* * * * *

(c) Except as provided under paragraph (d) of this section, when two or more fuels are combusted simultaneously, the applicable standard is determined by proration using the following formula:

* * * * *

(d)(1) On and after the date on which the initial performance test required to be conducted under § 60.8 is completed,

no new source owner or operator subject to the provisions of this subpart shall cause to be discharged into the atmosphere from any affected facility for which construction commenced after July 9, 1997 any gases which contain nitrogen oxides (expressed as NO_2) in excess of 200 nanograms per joule 1.6 pounds per megawatt-hour) gross energy output, based on a 30-day rolling average.

(2) On and after the date on which the initial performance test required to be conducted under § 60.8 is completed, no existing source owner or operator subject to the provisions of this subpart shall cause to be discharged into the atmosphere from any affected facility for which modification or reconstruction commenced after July 9, 1997 any gases which contain nitrogen oxides (expressed as NO_2) in excess of 65 ng/J_I (0.15 pounds per million Btu) heat input, based on a 30-day rolling average.

5. Section 60.46a is amended by adding paragraph (i) to read as follows:

§ 60.46a Compliance provisions.

* * * * *

(i) *Compliance provisions for sources subject to § 60.44a(d).* (1) The owner or operator of an affected facility subject to § 60.44a(d)(1) (new source constructed after July 7, 1997) shall calculate NO_X emissions by multiplying the average hourly NO_X output concentration measured according to the provisions of § 60.47a(c) by the average hourly flow rate measured according to the provisions of § 60.47a(1) and divided by the average hourly gross heat rate measured according to the provisions of § 60.47a(k).

(2) The owner or operator of an affected facility subject to § 60.44a(d)(2) (modified or reconstructed source after July 7, 1997) shall demonstrate compliance according to the provisions of paragraph (g) of this section.

6. Section 60.47a is amended by revising paragraph (c) and by adding paragraphs (k) and (l) to read as follows:

§ 60.47a Emission monitoring.

* * * * *

(c)(1) The owner or operator of an affected facility shall install, calibrate, maintain, and operate a continuous monitoring system, and record the output of the system, for measuring nitrogen oxides emissions discharged to the atmosphere; or

(2) If the owner or operator has installed a nitrogen oxides emission rate continuous emission monitoring system (CEMS) to meet the requirements of part 75 of this chapter and is continuing to meet the ongoing requirements of part 75 of this chapter, that CEMS may be used to meet the requirements of this section, except that the owner or operator shall also meet the requirements of § 60.49a. Data reported to meet the requirements of § 60.49a shall not include data substituted using the missing data procedures in subpart D of part 75 of this chapter, nor shall the data have been bias adjusted according to the procedures of part 75 of this chapter.

* * * * *

(k) The procedures specified in paragraphs (k)(1) through (k)(3) of this section shall be used to determine gross heat rate for sources demonstrating compliance with the output-based standard under § 60.44a(d)(1).

(1) The owner or operator of an affected facility with electricity generation shall install, calibrate, maintain, and operate a wattmeter; measure gross electrical output in megawatt-hour on a continuous basis; and record the output of the monitor.

(2) The owner or operator of an affected facility with process steam generation shall install, calibrate, maintain, and operate meters for steam flow, temperature, and pressure; measure gross process steam output in joules per hour (or Btu per hour) on a continuous basis; and record the output of the monitor.

(3) For affected facilities generating process steam in combination with electrical generation, the gross energy output is determined from the gross electrical output measured in accordance with paragraph (k)(1) of this section plus 50 percent of the gross thermal output of the process steam measured in accordance with paragraph (k)(2) of this section.

(l) The owner or operator of an affected facility demonstrating compliance with the output-based standard under § 60.44a(d)(1) shall, install, certify, operate, and maintain a continuous flow monitoring system, and record the output of the system, for measuring the flow of exhaust gases discharged to the atmosphere.

7. Section 60.49a is amended by revising the first sentence of paragraph (i) and adding paragraph (j) to read as follows:

§ 60.49a Reporting requirements.

* * * * *

(i) Except as provided in paragraph (j) of this section, the owner or operator of an affected facility shall submit the written reports required under this section and subpart A of this part to the Administrator for every calendar quarter. * * *

(j) The owner or operator of an affected facility may submit electronic quarterly reports for SO_2 and/or NO_X and/or opacity in lieu of submitting the written reports required under paragraphs (b) and (h) of this section. The format of each quarterly electronic report shall be coordinated with the permitting authority. The electronic report(s) shall be submitted no later than 30 days after the end of the calendar quarter and shall be accompanied by a certification statement from the owner or operator, indicating whether compliance with the applicable emission standards and minimum data requirements of this subpart was achieved during the reporting period. Before submitting reports in the electronic format, the owner or operator shall coordinate with the permitting authority to obtain their agreement to submit reports in this alternative format.

Subpart Db—[Amended]

8. Section 60.40b is amended by adding paragraphs (h) and (i) to read as follows:

§ 60.40b Applicability and delegation of authority.

* * * * *

(h) Affected facilities which meet the applicability requirements under subpart Eb (Standards of performance for municipal waste combustors; § 60.50b) are not subject to this subpart.

(i) Unless and until subpart GG of this part is revised to extend the applicability of subpart GG of this part to steam generator units subject to this subpart, this subpart will continue to apply to combined cycle gas turbines that are capable of combusting more than 29 MW (100 million Btu/hour) heat input of fossil fuel in the steam generator. Only emissions resulting from combustion of fuels in the steam generating unit are subject to this subpart. (The gas turbine emissions are subject to subpart GG of this part.)

9. Section 60.44b is amended by revising paragraphs (a) introductory text, (b) introductory text, (c), and (e) introductory text and by adding paragraph (l) to read as follows:

§ 60.44b Standard for nitrogen oxides.

(a) Except as provided under paragraphs (k) and (l) of this section, on and after the date on which the initial performance test is completed or is required to be completed under § 60.8 of this part, whichever date comes first, no owner or operator of an affected facility that is subject to the provisions of this section and that combusts only coal, oil, or natural gas shall cause to be discharged into the atmosphere from that affected facility any gases that

contain nitrogen oxides (expressed as NO_2) in excess of the following emission limits:

* * * * *

(b) Except as provided under paragraphs (k) and (l) of this section, on and after the date on which the initial performance test is completed or is required to be completed under § 60.8 of this part, whichever date comes first, no owner or operator of an affected facility that simultaneously combusts mixtures of coal, oil, or natural gas shall cause to be discharged into the atmosphere from that affected facility any gases that contain nitrogen oxides in excess of a limit determined by the use of the following formula:

* * * * *

(c) Except as provided under paragraph (l) of this section, on and after the date on which the initial performance test is completed or is required to be completed under § 60.8 of this part, whichever date comes first, no owner or operator of an affected facility that simultaneously combusts coal or oil, or a mixture of these fuels with natural gas, and wood, municipal-type solid waste, or any other fuel shall cause to be discharged into the atmosphere any gases that contain nitrogen oxides in excess of the emission limit for the coal or oil, or mixtures of these fuels with natural gas combusted in the affected facility, as determined pursuant to paragraph (a) or (b) of this section, unless the affected facility has an annual capacity factor for coal or oil, or mixture of these fuels with natural gas of 10 percent (0.10) or less and is subject to a federally enforceable requirement that limits operation of the affected facility to an annual capacity factor of 10 percent (0.10) or less for coal, oil, or a mixture of these fuels with natural gas.

* * * * *

(e) Except as provided under paragraph (l) of this section, on and after the date on which the initial performance test is completed or is required to be completed under § 60.8 of this part, whichever date comes first, no owner or operator of an affected facility that simultaneously combusts coal, oil, or natural gas with byproduct/waste shall cause to be discharged into the atmosphere any gases that contain nitrogen oxides in excess of the emission limit determined by the following formula unless the affected facility has an annual capacity factor for coal, oil, and natural gas of 10 percent (0.10) or less and is subject to a federally enforceable requirement that limits operation of the affected facility to an annual capacity factor of 10 percent (0.10) or less:

* * * * *

(l) On and after the date on which the initial performance test is completed or is required to be completed under § 60.8 of this part, whichever date comes first, no owner or operator of an affected facility which commenced construction, modification, or reconstruction after July 9, 1997 shall cause to be discharged into the atmosphere from that affected facility any gases that contain nitrogen oxides (expressed as NO_2) in excess of the following limits:

(1) If the affected facility combusts coal, oil, or natural gas, or a mixture of these fuels, or with any other fuels: A limit of 86 ng/J_I (0.20 lb/million Btu) heat input unless the affected facility has an annual capacity factor for coal, oil, and natural gas of 10 percent (0.10) or less and is subject to a federally enforceable requirement that limits operation of the facility to an annual capacity factor of 10 percent (0.10) or less for coal, oil, and natural gas; or

(2) If the affected facility has a low heat release rate and combusts natural gas or distillate oil in excess of 30 percent of the heat input from the combustion of all fuels, a limit determined by use of the following formula:

$E_n = [(0.10 * H_{go})+(0.20 * H_r)]/(H_{go}+H_r)$

Where:

E_n is the NO_X emission limit, (lb/million Btu),

H_{go} is the heat input from combustion of natural gas or distillate oil, and

H_r is the heat input from combustion of any other fuel.

10. Section 60.48b is amended by revising paragraph (b) to read as follows:

§ 60.48b Emission monitoring for particulate matter and nitrogen oxides.

* * * * *

(b) Except as provided under paragraphs (g), (h), and (i) of this section, the owner or operator of an affected facility shall comply with either paragraphs (b)(1) or (b)(2) of this section.

(1) Install, calibrate, maintain, and operate a continuous monitoring system, and record the output of the system, for measuring nitrogen oxides emissions discharged to the atmosphere; or

(2) If the owner or operator has installed a nitrogen oxides emission rate continuous emission monitoring system (CEMS) to meet the requirements of part 75 of this chapter and is continuing to meet the ongoing requirements of part 75 of this chapter, that CEMS may be used to meet the requirements of this section, except that the owner or operator shall also meet the requirements of § 60.49b. Data reported to meet the requirements of § 60.49b shall not include data substituted using the missing data procedures in subpart D of part 75 of this chapter, nor shall the data have been bias adjusted according to the procedures of part 75 of this chapter.

* * * * *

11. Section 60.49b is amended by adding paragraph (v) to read as follows:

§ 60.49b Reporting and recordkeeping requirements.

* * * * *

(v) The owner or operator of an affected facility may submit electronic quarterly reports for SO_2 and/or NO_X and/or opacity in lieu of submitting the written reports required under paragraphs (h), (i), (j), (k) or (l) of this section. The format of each quarterly electronic report shall be coordinated with the permitting authority. The electronic report(s) shall be submitted no later than 30 days after the end of the calendar quarter and shall be accompanied by a certification statement from the owner or operator, indicating whether compliance with the applicable emission standards and minimum data requirements of this subpart was achieved during the reporting period. Before submitting reports in the electronic format, the owner or operator shall coordinate with the permitting authority to obtain their agreement to submit reports in this alternative format.

[FR Doc. 98–24733 Filed 9–15–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL—6157–1]

RIN 2060–AH74

National Emission Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; interpretation and technical amendment.

SUMMARY: Under the authority of the Clean Air Act, the EPA has promulgated standards at 40 CFR part 63, subpart S (63 FR 18504, April 15, 1998) to reduce hazardous air pollutant (HAP) emissions from the pulp and paper production source category. This rule is known as

the Pulp and Paper national emission standards for hazardous air pollutants (NESHAP) and is the air component of the integrated air and water rules for the pulp and paper industry, commonly known as the Pulp and Paper Cluster Rules.

Today's action makes interpretive amendments to certain regulatory text in the NESHAP regarding the applicability of a 10 percent excess emissions allowance for condensate treatment systems. The EPA is making these amendments in response to inquiries received since publication of the final standards on April 15, 1998.

DATES: These amendments are effective September 16, 1998.

ADDRESSES: *Air Docket.* Docket A–92–40, containing the supporting information for the original NESHAP and this action, is available for public inspection and copying between 8 a.m. and 5:30 p.m., Monday through Friday except for Federal holidays, at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (MC–6102), 401 M Street SW., Washington, DC 20460, or by calling (202) 260–7548. The docket is located at the above address in Room M–1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Shedd, Emissions Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number (919) 541–5397. For questions on compliance and applicability determinations, contact Mr. Seth Heminway, Office of Enforcement and Compliance Assurance (2223A), U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460, telephone number (202) 564–7017.

SUPPLEMENTARY INFORMATION:

Regulated Entities

The entities potentially affected by this action include:

Category	Examples of regulated entities
Industry	Pulp mills and integrated mills (mills that manufacture pulp and paper/paperboard) that chemically pulp wood fiber using the kraft process.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in the amendments to the regulation affected by this action. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in 63, subparts A and S of Title 40 of the Code of Federal Regulations.

Informational Contacts

If you have questions regarding the applicability of this action to a particular situation, or questions about compliance approaches, permitting, enforcement and rule determinations, please contact the appropriate regional representative below:

Region I:

Greg Roscoe, Chief, Air Pesticides & Toxics Enforcement Office, Office of Environmental Stewardship, U.S. EPA, Region I, JFK Federal Building (SEA), Boston, MA 02203, (617) 565–3221 Technical Contact for Applicabilty Determination, Susan Lancey, (617) 565–3587, (617) 565–4940 Fax

Region II:

Mosey Ghaffari, Air Compliance Branch, U.S. EPA, Region II, 290 Broadway, New York, NY 10007–1866, (212) 637–3925, (212) 637–3998 Fax

Region III:

Makeba Morris, U.S. EPA, Region III, 3AT10, 841 Chestnut Building, Philadelphia, PA 19107, (215) 566–2187

Region IV:

Lee Page, U.S. EPA, Region IV, Atlanta Federal Center, 100 Alabama Street, Atlanta, GA 30303, (404) 562–9131

Region V:

Christina Prasinos (AE–17J), U.S. EPA, Region V, 77 West Jackson Street, Chicago, IL 60604–3590, (312) 886–6819 (312) 353–8289

Region VI:

Michelle Kelly, Air Enforcement Branch (6EN–AA), U.S. EPA, Region VI, Suite 1200, 1445 Ross Avenue, Dallas, TX 75202–2733 (214) 665–7580, (214) 665–7446 Fax

Region VII:

Gary Schlicht, Air Permits and Compliance Branch, U.S. EPA, Region VII, ARTD/APCO, 726 Minnesota Avenue, Kansas City, KS 66101, (913) 551–7097

Region VIII:

Tami Thomas-Burton, Air Toxics Coordinator, U.S. EPA, Region VIII, Suite 500, 999 18th Street, Denver, CO 80202–2466 (303) 312–6581, (303) 312–6064 Fax

Region IX:

Ken Bigos, U.S. EPA, Region IX, A–5, 75 Hawthorne Street, San Francisco, CA (415) 744–1240

Region X:

Andrea Wallenweber, Office of Air Quality, U.S. EPA, Region X, OAQ–107, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553–8760, (206) 553–0404 Fax

Technology Transfer Network

The Technology Transfer Network (TTN) is one of EPA's electronic bulletin boards. The TTN provides information and technology exchange in various areas of air pollution control. New air regulations are now being posted on the TTN through the world wide web at ''http://www.epa.gov/ttn.'' For more information on the TTN, call the HELP line at (919) 591–5384.

Outline

The information presented in this preamble is organized as follows:

I. Description of Amendments and Interpretations

In today's action, the EPA is amending § 63.446(g) to make clear the EPA's original intent regarding the applicability of the 10 percent excess emissions allowance to control devices used to treat kraft pulp mill condensates to comply with the requirements of § 63.446(e)(3) through (e)(5). The EPA made clear in the April 15, 1998 preamble at 63 FR 18529–30 that based on data submitted by the pulp and paper industry, EPA has concluded that some allowance for excess emissions is part of the maximum achievable control technology (MACT) floor level of control. EPA did not qualify this statement by saying that only particular technologies would require some type of allowance for excess emissions.

The EPA had previously shown (61 FR 9390–91, March 8, 1996) that the MACT floor level of control for pulping condensates at both bleached and unbleached kraft mills is treating the condensate streams to remove 92 percent of the HAP content (measured as methanol), or equivalently, to achieve an outlet concentration of less than 330 and 210 parts per million by weight (ppmw) measured as methanol or remove 9.2 and 5.9 pounds of methanol per air dried ton of pulp (10.2 and 6.6 pounds of methanol per oven dried ton of pulp (ODP) basis in the final rule) across the control device, respectively

for bleached and unbleached wastewater streams. The MACT floor control technology basis for these treatment options is steam stripping. Since steam stripping is the MACT floor control technology basis for the treatment requirements, the EPA also based the excess emissions allowance on steam stripping and determined that to be 10 percent. Therefore, the MACT floor-level of control is a combination of treatment requirements and an excess emissions allowance. The discussion in the March 8, 1996 supplemental notice at 61 FR 9390 further states that ''The rule would allow mills to: (1) Choose any wastewater treatment device as long as the device achieves one of the three parameters . . .'' (percent removal, ppmw outlet concentration, or mass per ODP removal).

The April 15, 1998 preamble and the March 8, 1996 supplemental notice clearly show that the EPA's intent was to provide mills flexibility in what control technology is used and what treatment option (set out at § 63.446(e)(3) through (e)(5)) is selected to comply with the MACT requirements for condensate treatment. Since the MACT requirements are a combination of treatment requirements and a downtime allowance, it is reasonable to interpret that any control device meeting the MACT requirements would be permissible—and this in fact is what EPA intended. However, the rule language is at variance with this preamble language because it limits the availability of the 10 percent excess emissions allowance to steam strippers complying only with the 92 percent methanol removal option. Since this rule language does not reflect EPA's intent (as shown in the preambles, as just discussed), EPA is correcting the rule language in today's notice.

The preamble to the final NESHAP at 63 FR 18529–30 describes excess emission allowances to include periods when the control device is inoperable and when the operating parameter values established during the initial performance test cannot be maintained at the appropriate level. The preamble further explains that the 10 percent excess emissions for condensate treatment includes periods of startup, shutdown, and malfunction allowances of the General Provisions to part 63. Since the MACT floor (both the treatment level and the excess emissions allowance) was based on steam stripping, the EPA discussed in the preamble likely problems that would necessitate an excess emissions allowance in the context of steam stripping operations. These were given as steam stripper downtime as a result of damage to the steam stripping system and loss of treatment efficiency resulting primarily from contamination of condensate with carryover of fiber or black liquor, steam supply downtime, and combustion control device downtime. (Control device downtime is a factor because the steam stripper should not be operated during periods when the stripper system vents cannot be routed to a control device). The EPA believes that these types of problems would necessitate this same downtime allowance, even with control devices other than steam strippers. An exception to this is where a mill elects to treat the condensate by discharging it below the liquid surface of a biological treatment system (see § 63.446(e)(2)) that is part of their wastewater treatment plant. These types of biological treatment systems are different than steam strippers and other control devices in terms of their excess emissions allowance needs for several reasons. First, steam strippers and most other control devices are typically located in or near the process, may be integrated into part of the process, and treat primarily, and usually exclusively, condensates. All of these factors make the control device vulnerable to downtime periods, even at the best operating mills. A similar concept of downtime does not translate to biological wastewater treatment systems, which accept wastewaters from all over the mill and must be up and running at all times to comply with National Pollutant Discharge Elimination System (NPDES) requirements under the Clean Water Act. Second, at steam strippers and other in-process type condensate control devices, periods when the operating parameter values (established during the initial performance test) cannot be maintained at the appropriate level count toward the 10 percent excess emissions allowance; however, for reasons set forth in the preamble at 63 FR 18523–24, biological wastewater treatment units are provided a unique set of parameter excursion provisions at § 63.453(p). Therefore, since the reasons for providing the 10 percent excess emissions allowance do not fit the biological wastewater treatment scenario and since the rule sets forth separate operating parameter excursion provisions for biological wastewater treatment, the EPA believes that it is reasonable to interpret the rule such that the 10 percent excess emissions allowance does not apply to biological wastewater treatment and is correcting the rule in today's action to reflect this interpretation.

Finally, since promulgation of the NESHAP, the EPA has become aware that there is some confusion over what is meant in the rule by the term ''biological treatment'' since the industry uses the term to refer to two different types of units. Today's action provides guidance but no rule changes to clarify how the rule applies to these two types of units. The issue has been raised by companies considering anaerobic biological treatment systems instead of steam strippers to comply with the condensate treatment requirements. The term, as used in the rule (see §§ 63.446(e)(2); 63.453(j) and (p); and 63.457(l)), refers to systems installed as part of the mill's wastewater treatment system primarily for purposes of complying with NPDES requirements under the Clean Water Act. The units are characteristically open to the atmosphere, require modeling in lieu of direct air emissions measurement during the initial performance test, and handle all of the mill's wastewater. These biological treatment systems are different than in-process type biological treatment systems, such as enclosed anaerobic treatment systems that can be directly measured for air emissions during the initial performance test and that would be installed primarily to treat condensate streams subject to the final pulp and paper NESHAP. This type of anaerobic system would be used instead of a steam stripper to comply with the treatment requirements at § 63.446(e)(3) through (e)(5) and thus, the excess emissions allowance at § 63.446(g) would apply, but (correspondingly) the operating parameter excursion provisions for biological wastewater treatment systems at § 63.453(p) would not apply. Also, it is important to note that since this anaerobic treatment system is serving the same function as a steam stripper (i.e. treatment of pulping condensates), it meets the rule definition of low volume high concentration system equipment and is thus subject to all of the pulping system requirements at § 63.443.

II. Administrative Requirements

A. Paperwork Reduction Act

The information requirements of the previously promulgated NESHAP were submitted for approval to the Office of Management and Budget (OMB) on April 27, 1998 under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1657.03), and a copy may be obtained from Sandy Farmer, OPPE Regulatory Information Division; U.S.

Environmental Protection Agency (2137); 401 M St., SW.; Washington, DC 20460 or by calling (202) 260–2740. The information requirements are not effective until OMB approves them.

Today's amendments to the NESHAP will have no impact on the information collection burden estimates made previously. The changes are interpretations of requirements and are not additional requirements. Consequently, the ICR has not been revised.

B. Executive Order 12866

Under Executive Order 12866, the EPA must determine whether the proposed regulatory action is ''significant'' and, therefore, subject to the OMB review and the requirements of the Executive Order. The Order defines ''significant'' regulatory action as one that is likely to lead to a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety in State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The NESHAP subpart S rule published on April 15, 1998, was considered significant under Executive Order 12866, and a regulatory impact analysis (RIA) was prepared. The amendments published today interpret the rule. The OMB has evaluated this action, and determined it to be nonsignificant; thus it did not require their review.

C. Regulatory Flexibility

Today's action is not subject to notice and comment rulemaking requirements and therefore is not subject to the Regulatory Flexibility Act. However, for the reasons discussed in the April 15, 1998 **Federal Register** (63 FR 18611–12), this rule does not have a significant impact on a substantial number of small entities. The changes to the rule in today's action do not add new control requirements to the April 15, 1998 rule.

D. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), the EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, the EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the action promulgated today does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate or to the private sector. Therefore, the requirements of the Unfunded Mandates Act do not apply to this action.

E. Executive Order 12875: Enhancing Intergovernmental Partnerships

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

While the final rule published on April 15, 1998 does not create mandates upon State, local, or tribal governments, EPA involved State and local governments in its development. Because the final regulation imposes costs to the private sector in excess of $100 million, the EPA pursued the preparation of an unfunded mandates statement and the other requirements of the Unfunded Mandates Reform Act. Because today's action interprets the requirements of the final rule, today's action does not create a mandate on State, local, or tribal governments. Today's action does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to today's action.

F. Applicability of Executive Order 13045

The Executive Order 13045 applies to any rule that EPA determines (1) economically significant as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the EPA must evaluate the environmental health or safety effects of the planned rule on children; and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the EPA.

Today's action is not subject to E.O. 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

G. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that

significantly or uniquely affect their communities.''

Today's action does not significantly or uniquely affect the communities of Indian tribal governments. The final rule published on April 15, 1998 does not create mandates upon tribal governments. Because today's action interprets the requirements of the final rule, today's action does not create a mandate on tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this action.

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) directs all Federal agencies to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test methods, sampling and analytical procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American Society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive Engineers (SAE). The NTTAA requires Federal agencies like EPA to provide Congress, through OMB, with explanations when an agency decides not to use available and applicable voluntary consensus standards.

This action does not involve any new technical standards or the incorporation by reference of existing technical standards. Therefore, consideration of voluntary consensus standards is not relevant to this action.

I. Immediate Effective Date

The EPA is making today's action effective immediately. The EPA has determined that the rule changes being made in today's action are interpretive rules which are not subject to notice and comment requirements. In addition, the rule change is a type of technical correction, since it amends the rule to be consistent with EPA's intentions stated in the rule's preamble. Notice and opportunity for comment is not required for such technical corrections. The EPA has also determined that this rule may be made effective in less than 30 days because it is interpretive, and relieves restrictions. See 5 U.S.C. 553 (d)(1) and (2).

J. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. However, section 808 provides that any rule for which the issuing agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule) that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of September 16, 1998. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

III. Legal Authority

These regulations are amended under the authority of sections 112, 114, and 301 of the Clean Air Act, as amended (42 U.S.C. sections 7412, 7414, and 7601).

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Pulp mills, Cluster Rules.

Dated: September 6, 1998.

Robert Perciasepe,

Assistant Administrator for Air and Radiation.

For the reasons set out in the preamble, title 40, Chapter I of the Code of Federal Regulations is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart S—National Emission Standards for Hazardous Air Pollutants from the Pulp and Paper Industry

2. Section 63.446 is amended by revising paragraph (g) to read as follows:

§ 263.446 Standards for kraft pulping process condensates.

* * * * *

(g) For each control device (e.g. steam stripper system or other equipment serving the same function) used to treat pulping process condensates to comply with the requirements specified in paragraphs (e)(3) through (e)(5) of this section, periods of excess emissions reported under § 63.455 shall not be a violation of paragraphs (d), (e)(3) through (e)(5), and (f) of this section provided that the time of excess emissions (including periods of startup, shutdown, or malfunction) divided by the total process operating time in a semi-annual reporting period does not exceed 10 percent. The 10 percent excess emissions allowance does not apply to treatment of pulping process condensates according to paragraph (e)(2) of this section (e.g. the biological wastewater treatment system used to treat multiple (primarily non-condensate) wastewater streams to comply with the Clean Water Act).

* * * * *

[FR Doc. 98–24837 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 69 and 80

[FRL–6159–1]

State of Alaska Petition for Exemption From Diesel Fuel Sulfur Requirement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On December 12, 1995, the Governor of Alaska petitioned EPA to permanently exempt the areas of Alaska served by the Federal Aid Highway System from the requirements of EPA's low-sulfur diesel fuel program for motor vehicles. On August 19, 1996, EPA extended the existing temporary exemption until October 1, 1998, and on April 28, 1998, EPA proposed to grant a permanent exemption (63 FR 23241). EPA has received significant public comments and new information concerning EPA's proposal and needs additional time to further evaluate the issues concerning a permanent exemption. Consequently, EPA is

granting a temporary exemption to Alaska for a period of nine months (i.e., until July 1, 1999) so that EPA and the State of Alaska have ample time to consider and evaluate the public comments and new information before EPA makes a final decision on the petition.

This decision is not expected to have a significant impact on the ability of Alaska's communities to attain the National Ambient Air Quality Standards for carbon monoxide and particulate matter, due to the limited contribution of emissions from diesel motor vehicles in those areas and the sulfur level currently found in motor vehicle diesel fuel used in Alaska.

DATES: This final rule is effective on October 1, 1998.

ADDRESSES: Copies of information relevant to this final rule are available for inspection in public docket A–96–26 at the Air Docket of the EPA, first floor, Waterside Mall, room M–1500, 401 M Street SW, Washington, DC 20460, (202) 260–7548, between the hours of 8 a.m. to 5:30 p.m. Monday through Friday. A duplicate public docket has been established at EPA Alaska Operations Office-Anchorage, Federal Building, Room 537, 222 W. Seventh Avenue, #19, Anchorage, AK 99513–7588, and is available from 8 a.m. to 5 p.m. Monday through Friday. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Babst, Environmental Engineer, Fuels Implementation Group, Fuels and Energy Division (6406–J), 401 M Street SW, Washington, DC 20460, Telephone (202) 564–9473, Telefax 202–565–2085, Internet address babst.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Regulated Entities

Entities potentially regulated by this action are refiners, marketers, distributors, retailers and wholesale purchaser-consumers of diesel fuel for use in the state of Alaska. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Petroleum distributors, marketers, retailers (service station owners and operators), wholesale purchaser consumers (fleet managers who operate a refueling facility to refuel motor vehicles).
Individuals	Any owner or operator of a diesel motor vehicle.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the criteria contained in § 69.51, § 80.29, and § 80.30 of title 40 of the Code of Federal Regulations as modified by today's action. If you have questions regarding the applicability of this action to a particular entity, consult one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Electronic Copies of Rulemaking Documents

The preamble and regulatory language are also available electronically from the Government Printing Office Web sites. This service is free of charge, except for any cost you already incur for Internet connectivity. The electronic **Federal Register** version is made available on the day of publication on the Web site listed below.

http://www.access.gpo.gov/nara/cfr/ (either select desired date or use Search feature)

Please note that due to differences between the software used to develop the document and the software into which the document may be downloaded, changes in format, page length, etc. may occur.

III. Statutory Background

Section 211(i)(1) of the Act prohibits the manufacture, sale, supply, offering for sale or supply, dispensing, transport, or introduction into commerce of motor vehicle diesel fuel which contains a concentration of sulfur in excess of 0.05 percent by weight, or which fails to meet a cetane index minimum of 40 beginning October 1, 1993. Section 211(i)(2) requires the Administrator to promulgate regulations to implement and enforce the requirements of paragraph (1), and authorizes the Administrator to require that diesel fuel not intended for motor vehicles be dyed in order to segregate that fuel from motor vehicle diesel fuel. Section 211(i)(4) provides that the States of Alaska and Hawaii may seek an exemption from the requirements of subsection 211(i) in the same manner as provided in section 325 [1] of the Act, and requires the Administrator to take final action on any petition filed under this subsection, which seeks exemption from the requirements of section 211(i), within 12 months of the date of such petition.

Section 325 of the Act provides that upon application by the Governor of Guam, American Samoa, the Virgin Islands, or the Commonwealth of the Northern Mariana Islands, the Administrator may exempt any person or source, or class of persons or sources, in such territory from any requirement of the Act, with some specific exceptions. Such exemption may be granted if the Administrator finds that compliance with such requirement is not feasible or is unreasonable due to unique geographical, meteorological, or economic factors of such territory, or such other local factors as the Administrator deems significant.

IV. Petition for Exemption

On February 12, 1993, the Honorable Walter J. Hickel, then Governor of the State of Alaska, submitted a petition to exempt motor vehicle diesel fuel in Alaska from subsections (1) and (2) of section 211(i), except the minimum cetane index requirement of 40. Paragraph (1) prohibits motor vehicle diesel fuel from having a sulfur concentration greater than 0.05 percent by weight, or failing to meet a minimum cetane index of 40. Paragraph (2) requires the Administrator to promulgate regulations to implement

[1] Section 211(i)(4) mistakenly refers to exemptions under § 324 of the Act (''Vapor Recovery for Small Business Marketers of Petroleum Products''). The proper reference is to § 325, and Congress clearly intended to refer to § 325, as shown by the language used in § 211(i)(4), and the United States Code citation used in § 806 of the Clean Air Act Amendments of 1990, Public Law No. 101–549. Section 806 of the Amendments, which added paragraph (i) to § 211 of the Act, used 42 U.S.C. 7625–1 as the United States Code designation, the proper designation for § 325 of the Act. Also see 136 Cong. Rec. S17236 (daily ed. October 26, 1990) (statement of Sen. Murkowski).

and enforce the requirements of paragraph (1), and authorizes the Administrator to require that diesel fuel not intended for motor vehicles be dyed in order to segregate that diesel fuel from motor vehicle diesel fuel. The petition requested that the Environmental Protection Agency (EPA) temporarily exempt motor vehicle diesel fuel manufactured for sale, sold, supplied, or transported within the Federal Aid Highway System from meeting the sulfur content requirement specified in section 211(i) until October 1, 1996. The petition also requested a permanent exemption from such requirements for those areas of Alaska not reachable by the Federal Aid Highway System. The petition was based on geographical, meteorological, air quality, and economic factors unique to the State of Alaska.

EPA's decision on the petition was published on March 22, 1994 (59 FR 13610), and applied to all persons in Alaska subject to section 211(i) and related provisions in section 211(g) of the Act and EPA's low-sulfur requirement for motor vehicle diesel fuel in 40 CFR 80.29. Persons in communities served by the Federal Aid Highway System were exempted from compliance with the diesel fuel sulfur content requirement until October 1, 1996. Persons in communities that are not served by the Federal Aid Highway System were permanently exempted from compliance with the diesel fuel sulfur content requirement. Both the permanent and temporary exemptions apply to all persons who manufacture, sell, supply, offer for sale or supply, dispense, transport, or introduce into commerce, in the State of Alaska, motor vehicle diesel fuel. Alaska's exemptions do not apply to the minimum cetane requirement for motor vehicle diesel fuel.

On December 12, 1995, the Honorable Governor Tony Knowles, Governor of the State of Alaska, petitioned the Administrator for a permanent exemption (Petition) for all areas of the state served by the Federal Aid Highway System, that is, those areas covered only by the temporary exemption. On August 19, 1996, EPA published an extension to the temporary exemption until October 1, 1998 (61 FR 42812), to give ample time for the agency to consider comments to that petition that were subsequently submitted. On April 28, 1998 (63 FR 23241) EPA published a proposal to grant the petition for a permanent exemption for all areas of the state served by the Federal Aid Highway System. Substantial public comments and substantive new information was submitted in response to the proposal.

V. Decision for Temporary Exemption

In this document, the Agency is granting a temporary exemption for nine months (until July 1, 1999) from the diesel fuel sulfur content requirement of 0.05 percent by weight to those areas in Alaska served by the Federal Aid Highway System. For the same reasons, the Agency also is granting a temporary exemption for nine months from those provisions of section 211(g)(2)[2] of the Act that prohibit the fueling of motor vehicles with high-sulfur diesel fuel. Sections 211(g) and 211(i) both restrict the use of high-sulfur motor vehicle diesel fuel.

Further, consistent with the March 22, 1994 Notice of Final Decision (59 FR 13610), dyeing diesel fuel to be used in nonroad applications will be unnecessary in Alaska during the temporary exemption as long as the diesel fuel has a minimum cetane index of 40. The motor vehicle diesel fuel regulations, codified at 40 CFR 80.29, provide that any diesel fuel which does not show visible evidence of the dye solvent red 164 shall be considered to be available for use in motor vehicles and subject to the sulfur and cetane index requirements. The Alaska Department of Environmental Conservation and various refiners in Alaska have indicated to EPA that all diesel fuel manufactured for sale and marketed in Alaska for use in both motor vehicle and nonroad applications meets the minimum cetane requirement for motor vehicle diesel fuel.

Justification for Temporary Exemption

Section 325 of the Clean Air Act Amendments of 1990 provide that an exemption may be granted due to ''such other local factors as the Administrator deems significant.'' Alaska has operated under temporary exemptions for the past several years. EPA has indicated to Alaska that EPA would make a final decision on whether to grant a permanent exemption from the low sulfur diesel fuel requirements. EPA will not have made a final decision on a permanent exemption prior to the expiration of the current temporary exemption. EPA believes that requiring compliance in Alaska with diesel fuel sulfur requirements during the nine months before such a final decision is published is unreasonable, given the unique circumstances associated with this prior history of exemptions, and EPA's need for additional time to make a final decision on Alaska's request for a permanent exemption. These significant local factors are the basis for granting Alaska this extension to the current temporary exemption.

In response to the February 12, 1993 petition for a temporary exemption from diesel fuel sulfur requirements for areas served by the FAHS, EPA granted Alaska the temporary exemption until October 1, 1996. Because the state of Alaska planned to establish a Task Force (in which an EPA representative participated) to evaluate the need for an exemption, EPA provided Alaska with ''adequate time to prepare and submit another exemption request'' (59 FR 13613, March 22, 1994). ''If a new exemption request is submitted, EPA will publish another notice in the **Federal Register** and re-examine the issue of an exemption.'' *Id.*

In response to the December 12, 1995, petition for a permanent exemption from the diesel sulfur requirements for the areas served by the FAHS, EPA ''reserv[ed] the decision on the state's request for a permanent exemption, so the agency may consider possible alternatives for a longer period'' than the two years granted (61 FR 42814, August 19, 1996). EPA extended for another period of 24 months ''or until such time as a decision is made on the permanent exemption, whichever is shorter'' (61 FR 42816, August 19, 1996). EPA also stated that ''areas in Alaska served by the Federal Aid Highway System are also exempt from the related 211(g)(2) provisions until such time as a decision has been made on the state's petition for a permanent exemption.'' *Id.* The Agency stated it would propose a decision on Alaska's request for a permanent waiver. *Id.*

EPA did not intend that Alaska would be required to comply with the low-sulfur diesel requirements before reaching a final decision. Unfortunately, a decision will not be reached before the current temporary exemption expires. EPA proposed to permanently exempt Alaska (63 FR 23241, April 28, 1998), and received significant comments on several issues and new information during this notice and comment period critical to the question of whether Alaska should be granted an exemption to the low-sulfur diesel fuel requirements.

One issue that will require additional time for EPA to evaluate involves the

[2] This subsection makes it unlawful for any person to introduce or cause or allow the introduction into any motor vehicle of diesel fuel which they know or should know contains a concentration of sulfur in excess of 0.05 percent (by weight). It would clearly be impossible to hold persons liable for misfueling with diesel fuel with a sulfur content higher than 0.05 percent by weight, when such fuel is permitted to be sold or dispensed for use in motor vehicles. The proposed exemptions would include exemptions from this prohibition, but not include the prohibitions in § 211(g)(2) relating to the minimum cetane index or alternative aromatic levels.

use of high-sulfur diesel fuel in engines manufactured to meet future more stringent emissions standards. In their comments to the proposal, the Engine Manufacturers Association (EMA) asserted in part, that the use of high-sulfur diesel fuel in advanced technology engines, especially those engines that will be in the marketplace to meet 2004 emission standards, will result in excessive engine wear, poor durability, substantially increased maintenance costs, substandard performance, and in some cases, engine failure. EMA indicated that these advanced technologies are expected to be introduced before 2004, and are only feasible if operated on low-sulfur fuel. EPA believes some manufacturers may implement these advanced technologies as early as 2002.

The technology of most concern is the cooled exhaust gas recirculation (EGR) system. In an EGR system, exhaust gas is recirculated back into the cylinders to reduce the amount of fresh charge air or oxygen that is available for combustion during certain operating conditions. Combustion temperatures, and thus nitrogen oxides (NO_X) formation, are reduced. In order to maximize the effectiveness of the EGR system, the exhaust gas is cooled before it enters the fresh air stream. According to the EMA, when the engine is operated on high-sulfur diesel fuel, sulfur in the exhaust gas stream is condensed by the EGR cooler and forms sulfuric acid deposits in the cooler and any surfaces through which the cooled exhaust gas passes. Thus, the combination of high-sulfur and cooled EGR systems will promote corrosion in the EGR cooler and control valve, power cylinder and induction system, will cause wear and tear on the power cylinder, and will result in the formation of deposits on the EGR cooler and induction system. The EMA indicates that while more frequent replacement of the EGR and air intake components may reduce the sulfuric acid damage to the EGR system, it is not possible to eliminate the damage.

EPA has determined that an additional nine months is necessary to evaluate the information to determine whether Alaska should be granted a permanent exemption to the low-sulfur diesel fuel requirements. EPA believes that requiring Alaska to incur the cost and burden associated with compliance until EPA reaches a final decision is unreasonable, given the expectation that EPA will make a final decision in the next several months, and the possibility that EPA may then decide to grant the exemption. In addition, EPA believes that in this situation lead-time considerations are also a significant local factor as provided under section 325. Requiring Alaska to comply with low-sulfur diesel fuel requirements as of October 1998 is unreasonable due to lead-time considerations. Because of the temporary status of the previous and current exemptions, EPA did not intend that Alaska would be required to comply prior to a final decision on a permanent exemption. Therefore, the affected parties in Alaska are not in a position to reasonably comply prior to such a final decision. Alaska has recently indicated to EPA that at least three years would be needed to implement any new requirements once a final decision has been reached by EPA. Requiring compliance by refiners and distributors and consumers of diesel fuel by October 1998 would not be reasonable under these circumstances.

Further, any expiration of the low-sulfur exemption has implications under the Internal Revenue Code. Section 4081 of the Internal Revenue Code (26 U.S.C. 4081) imposes a tax on the removal of diesel fuel from a terminal at the terminal rack. However, a tax is not imposed if, among other conditions, the diesel fuel is indelibly dyed in accordance with Treasury regulations. Dyed diesel fuel can be used legally (for tax purposes) in nontaxable uses such as for heating oil, fuel in stationary engines, or fuel in non-highway vehicles. A substantial penalty applies if dyed diesel fuel is used for taxable purposes such as in registered highway vehicles.

In 1996, Congress enacted an exception to the dyeing requirement so that undyed diesel fuel could be removed from a terminal tax free if, among other requirements, the fuel is removed for ultimate sale or use in an area of Alaska during the period the area is exempt from EPA's sulfur content and fuel dyeing requirements under section 211(i)(4) of the Clean Air Act. Treasury regulations (26 CFR 46.4082–5) generally establish a system for collecting the federal diesel fuel tax at the wholesale level in Alaska. This system is similar to the system used by the state of Alaska for state fuel tax. The person liable for the federal tax generally is the person who is licensed by Alaska as a qualified dealer or a retailer that has been registered by the Internal Revenue Service (IRS).

If EPA's temporary exemption for the FAHS areas of Alaska were to expire, then under Treasury regulations, the federal fuel tax would be imposed on all undyed diesel fuel that is removed from any terminal in the FAHS areas, regardless of the use that is later made of the fuel. Removals from these terminals would be exempt from the tax only if the fuel contains a dye of a prescribed color and composition. Consequently, Alaska would be required by the Treasury regulations to either dye the non-road tax-exempt fuel or pay the on-road tax at the current rate of 24.4 cents per gallon.

According to an attachment to the comments submitted by the Trustees for Alaska, Alaska used approximately 600 million gallons of distillate each year (excluding fuel used for aviation) for the fiscal years ending June 30, 1996 and June 30, 1997. If none of that fuel were dyed and the sulfur exemption were to expire, the tax liability for Alaska (at 24.4 cents per gallon) would be approximately $146.4 million per year, compared to only $19.4 million per year if only that fuel used for highway purposes were taxed. The taxed parties could later file for refunds for the fuel they could show was not used in motor vehicles. Alternatively, Alaska could comply with the Treasury regulations by dyeing the approximately 86 percent of that fuel intended for non-highway use. However, to do so would be a significant and unreasonable burden for refiners, distributors and consumers of diesel fuel, especially if the lapse in the EPA exemption were only for a few months. Comments received in response to the proposal indicated that each additional storage tank needed to segregate the dyed and undyed fuels with supporting infrastructure may cost $600,000, and there are over 80 tank farms in Alaska that would require additional tankage. Similarly each additional tanker truck required to avoid cross-contamination of dyed and undyed fuels costs approximately $250,000. Finally, those comments indicated that significant lead-time would be needed.

Based on these significant local factors, it is unreasonable to mandate that low-sulfur motor vehicle diesel fuel be available for use in Alaska for areas served by the Federal Aid Highway System after the current temporary exemption expires on October 1, while EPA considers a final decision on the Petition.

Clarification of Exemption

Since today's rule exempts diesel fuel in Alaska from the sulfur requirement for nine months (i.e., until July 1, 1999), dyeing diesel fuel to be used in nonroad applications will be unnecessary in Alaska for those nine months. However, in the event high-sulfur diesel fuel is shipped from Alaska to the lower-48 states, it would be necessary for the producer or shipping facility to add dye to the noncomplying fuel before it is

introduced into commerce in the lower-48 states. In addition, supporting documentation (e.g., product transfer documents) must clearly indicate the fuel may not comply with the sulfur standard for motor vehicle diesel fuel and is not to be used as a motor vehicle fuel. Conversely, EPA will not require high-sulfur diesel fuel to be dyed if it is being shipped from the lower-48 states to Alaska, but supporting documentation must substantiate that the fuel is only for shipment to Alaska and that it may not comply with the sulfur standard for motor vehicle diesel fuel.

EPA will assume that all diesel fuel found in any state, except in the state of Alaska, is intended for sale in any state and subject to the diesel fuel standards, unless the supporting documentation clearly specifies the fuel is to be shipped only to Alaska. The documentation should further clearly state that the fuel may not comply with the Federal diesel fuel standards. If such product enters the market of any state, other than Alaska, (e.g., is on route to or at a dispensing facility in a state other than Alaska) and is found to exceed the applicable sulfur content standard, all parties will be presumed liable, as set forth in the regulations. However, EPA will consider the evidence in determining whether a party caused the violation.

With regard to the storage of diesel fuel in any state other than Alaska, a refiner or transporter will not be held liable for diesel fuel that does not comply with the applicable sulfur content standard and dye requirement if it can show that the diesel fuel is truly being stored and is not being sold, offered for sale, supplied, offered for supply, transported or dispensed. However, once diesel fuel leaves a refinery or transporter facility, a party can no longer escape liability by claiming that the diesel fuel was simply in storage. Although diesel fuel may temporarily come to rest at some point after leaving a refinery or transporter facility, the intent of the regulations is to cover all diesel fuel being distributed in the marketplace. Once diesel fuel leaves a refinery or shipping facility it is in the marketplace and as such is in the process of being sold, supplied, offered for sale or supply, or transported.

Engine Warranty, Recall and Tampering

EPA previously addressed the impact of an exemption from the low-sulfur diesel fuel requirements on engine recall liability, warranty and tampering issues in the American Samoa decision [3], Guam decision [4], and Alaska decision.[5] For this final rule, EPA is addressing the recall liability and warranty issues in a manner consistent with those earlier decisions. The tampering issue is treated in a somewhat different manner.

Recall Liability. If EPA determines that a substantial number of heavy-duty engines do not comply with the federal emission requirements, the engine manufacturer is responsible for recalling and repairing the engines. EPA typically determines whether engines comply with applicable federal emission standards when properly used and maintained based on testing of in-use engines. If an engine fueled with noncomplying diesel fuel were included in such testing, EPA will determine, on a case-by-case basis, if the noncompliance is the result of the use of noncomplying fuel. If it is determined that the noncomplying diesel fuel is the cause of the engine's failure to meet the applicable emission standards, EPA would take that into consideration before seeking a recall of the class.

For Alaska, as in the Guam and American Samoa decisions, the Agency does not intend to use test results (emissions levels) from engines that utilize high-sulfur diesel fuel (over 0.05% by weight) to show noncompliance by those engines for the purpose of recalling an engine class. However, in cases in which it is determined that the overall class is subject to recall for reasons other than noncomplying fuel in Alaska, individual engines will not be excluded from repair on the basis of the fuel used. Manufacturers are responsible for repairing any engine in the recalled class regardless of its history of tampering or improper maintenance.

Manufacturers Emission Warranty. The Agency acknowledges that engines that were certified to meet the federal emission standards using low-sulfur diesel fuel may in some cases be unable to meet those federal emissions standards if they use high-sulfur diesel fuel. However, EPA believes an exemption from the general warranty provisions of section 207 is unnecessary to protect manufacturers from unreasonable warranty recoveries by purchasers. The emission defect warranty requirements under section 207(a) of the Act require an engine manufacturer to warrant that the engine shall conform at the time of sale to applicable emission regulations and that the engine is free from defects that cause the engine to fail to conform with applicable regulations for its useful life. In practice, this warranty is applicable to a specific list of emissions and emissions-related engine components.

It has been consistent EPA policy that misuse or improper maintenance of a vehicle or engine by the purchaser, including misfueling, may create a reasonable basis for denying warranty coverage for the specific emissions and emissions-related engine components affected by the misuse. In Alaska, while use of fuel exempted from the sulfur content limitation cannot be considered ''misfueling,'' it will have the same adverse effect on emissions control components. Thus, EPA believes that where the use of noncomplying diesel fuel in fact has an adverse impact on the emissions durability of specific engine parts or systems, such as a catalyst, the manufacturer has a reasonable basis for denying warranty coverage on that part or other related parts. As has consistently been EPA's policy, those components not adversely affected by the use of noncomplying diesel fuel should continue to receive full emissions warranty coverage.

Tampering Liability. Subsequent to the 1995 petition for a permanent exemption from the diesel fuel sulfur requirements, the Engine Manufacturers Association (EMA) requested enforcement discretion regarding the removal of catalytic converters because of an indicated plugging problem caused by the high-sulfur diesel fuel in Alaska. However, information subsequently collected by EPA from several heavy-duty engine manufacturers demonstrates that catalyst plugging is mainly a cold weather problem and not a high-sulfur fuel issue. EPA is also aware that the majority of the plugged catalysts have been eliminated. In a letter to EPA of September 19, 1997, the EMA indicated that the immediate problems that led to EMA's earlier request have been resolved. Accordingly, EPA sees no need for an exemption that allows the removal of catalysts in the field, or that permits manufacturers to introduce into commerce catalyzed-engines without catalysts.

VI. Judicial Review

Under section 307(b)(1) of the Clean Air Act, EPA hereby finds that these regulations are of local or regional applicability. Accordingly, judicial

[3] The Agency granted American Samoa's petition for an exemption from the diesel sulfur requirements on July 20, 1992, 57 FR 32010.

[4] The Agency granted Guam's petition for an exemption from the diesel sulfur requirements on September 21, 1993, 58 FR 48968.

[5] The Agency granted the State of Alaska's petition for a temporary exemption from the diesel sulfur requirements on March 22, 1994, 59 FR 13610.

review of this action is available only in the United States Court of Appeals for the circuit applicable to Alaska within 60 days of publication.

VII. Public Participation

The Agency received Alaska's request for a permanent exemption for the Federal Aid Highway System areas in December of 1995. Soon afterwards, the Agency has received comments on the petition from the Alaska Center for the Environment, the Alaska Clean Air Coalition, and the Engine Manufacturers of America. EPA believed the issues raised by those comments and possible tightening of heavy-duty motor vehicle engine standards in 2004 necessitated further consideration before the Agency made a decision on Alaska's request for a permanent waiver.

The Agency published a proposed rule for a permanent exemption to allow interested parties an additional opportunity to request a hearing or to submit comments. EPA subsequently received a request for a public hearing, but that request was soon withdrawn. EPA extended the comment period until June 12, 1998, and received comments before and after that date.

EPA's decision to extend the exemption until July 1, 1999 is not a decision based on the merits of those comments. Instead, EPA's decision is based on the unreasonableness of imposing the low-sulfur diesel fuel requirement during the time period needed by EPA to make a final decision on the merits of the comments submitted. The significant local factors supporting this decision are described herein.

VIII. Statutory Authority

Authority for the action in this proposed rule is in sections 211 (42 U.S.C. 7545) and 325(a)(1) (42 U.S.C. 7625–1(a)(1)) of the Clean Air Act, as amended.

IX. Administrative Requirements

A. Executive Order 12866: Administrative Designation and Regulatory Analysis

Under Executive Order 12866,[6] the Agency must determine whether a regulation is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments of communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.[7]

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because today's action to extend the temporary exemption of the low-sulfur diesel fuel requirements in the State of Alaska, will not result in any additional economic burden on any of the affected parties, including small entities involved in the oil industry, the automotive industry and the automotive service industry. EPA is not imposing any new requirements on regulated entities, but instead is continuing an exemption from a requirement, which makes it less restrictive and less burdensome. Therefore, EPA has determined that this action will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 544 U.S.C. 3501 *et seq.*, and implementing regulations, 5 CFR part 1320, do not apply to this action as it does not involve the collection of information as defined therein.

D. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective October 1, 1998.

E. Unfunded Mandates Act

Under section 202 of the Unfunded Mandates Reform Act of 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate with estimated costs to the private sector of $100 million or more, or to state, local, or tribal governments of $100 million or more in the aggregate. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that this final rule imposes no new federal requirements and does not include any federal mandate with costs to the private sector or to state, local, or tribal governments. Therefore, the Administrator certifies that this rule does not require a budgetary impact statement.

F. Executive Order 12875: Enhancing Intergovernmental Partnerships

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to

[6] 58 FR 51736 (October 4, 1993).

[7] *Id.* at section 3(f)(1)–(4).

develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

G. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate if unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. EPA has determined that this final rule imposes no new federal requirements, but rather extends an existing temporary exemption of the low-sulfur diesel fuel requirements in the State of Alaska. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

H. Executive Order 13045: Children's Health Protection

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by E.O. 12866, and because it does not involve decisions based on environmental health or safety risks.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

List of Subjects

40 CFR Part 69

Environmental protection, Air pollution control, Alaska.

40 CFR Part 80

Environmental protection, Air pollution control, Diesel fuel, Motor vehicle pollution.

Dated: September 3, 1998.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40 chapter I of the Code of Federal Regulations is amended as follows:

PART 69—[AMENDED]

1. The authority citation for part 69 is revised to read as follows:

Authority: 42 U.S.C. 7545(1) and (g), 7625–1.

2. Subpart E consisting of § 69.51 is added to read as follows:

Subpart E—Alaska

§ 69.51 Exemptions.

(a) Persons in the state of Alaska, including but not limited to, refiners, importers, distributors, resellers, carriers, retailers or wholesale purchaser-consumers may manufacture, introduce into commerce, sell, offer for sale, supply, dispense, offer for supply, or transport diesel fuel, which fails to meet the sulfur concentration or dye requirements of 40 CFR 80.29, in the state of Alaska if the fuel is used only in the state of Alaska.

(b) Persons outside the state of Alaska, including but not limited to, refiners, importers, distributors, resellers, carriers, retailers or wholesale purchaser-consumers may manufacture, introduce into commerce, sell, offer for sale, supply, offer for supply, or transport diesel fuel, which fails to meet the sulfur concentration or dye requirements of § 80.29, outside the state of Alaska if the fuel is:

(1) Used only in the state of Alaska; and

(2) Accompanied by supporting documentation that clearly substantiates the fuel is for use only in the state of Alaska and does not comply with the Federal sulfur standard applicable to motor vehicle diesel fuel.

(c) Beginning July 1, 1999, the exemptions provided in paragraphs (a) and (b) of this section are applicable only to fuel used in those areas of Alaska that are not served by the Federal Aid Highway System.

PART 80—[AMENDED]

3. The authority citation for part 80 continues to read as follows:

Authority: Sec. 114, 211, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7414, 7545 and 7601(a)).

4. Section 80.29 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 80.29 Controls and prohibitions on diesel fuel quality.

(a) Prohibited activities. (1) Beginning October 1, 1993, no person, including but not limited to, refiners, importers, distributors, resellers, carriers, retailers or wholesale purchaser-consumers, shall manufacture, introduce into commerce, sell, offer for sale, supply, dispense, offer for supply or transport any diesel fuel for use in motor vehicles, except as provided in 40 CFR 69.51, unless the diesel fuel:

* * * * *

[FR Doc. 98–24734 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300698; FRL 6022–1]

RIN 2070–AB78

Trichoderma Harzianum Strain T-39; Exemption from the Requirement of a Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a temporary tolerance for residues of the *Trichoderma harzianum* strain T-39 in/on strawberry, table grape and wine grape when applied/used as ground or foliar applications in accordance with the provisions of experimental use permit 11678–EUP–1. Makhteshim-Agan of North America, Inc. submitted an amended petition PP 6G4622 to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting an exemption from the requirement of a temporary tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Trichoderma harzianum* strain T-39.

DATES: This regulation is effective September 16, 1998. Objections and requests for hearings must be received by EPA on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300698], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300698], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300698]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 902W34, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308–8097; e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 24, 1998, (63 FR 34390) (FRL 5795–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition by Makhteshim-Agan of North America Inc., 551 Fifth Ave., Suite 1100, New York, NY 10176. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a temporary tolerance for residues of the microbial antifungal agent *Trichoderma harzianum* strain T-39 in or on all food/feed commodities. The data which were evaluated for the Experimental Use Permit (EUP) granted in May of 1996 are sufficient to support the exemption from the requirement of a temporary tolerance in/on table grape, wine grape and strawberry. There were no comments received in response to the notice of filing. This exemption from the requirement of a tolerance will expire on November 30, 2000.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a temporary tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

A. Proposed Use

The rates, frequency and timing of the applications vary. The pesticide is to be applied by ground equipment as a foliar spray. Application rates are 2 to 4 pounds per acre per application from pre-bloom to harvest. One to four applications are made to wine grapes in a rotational program with conventional chemical fungicides, while four to six applications may be applied to wine grapes when the product is used alone. Table grapes are treated with one to three applications during pre-bloom to fruit set. Strawberry may be treated with one to eight applications once per week throughout the growing season from pre-bloom to harvest.

B. Product Chemistry

The data submitted for product identity of the active ingredient, *Trichoderma harzianum* strain T-39, and end use product, Trichodex, are acceptable for the limited use proposed for this EUP. The active ingredient, *Trichoderma harzianum*, is a naturally-occurring fungus which can be found in the US and in the environment worldwide. The microbial pesticide

contains dried solids and solubles resulting from the fermentation of *Trichoderma harzianum* isolate T-39, containing T-39 fungus propagules as either conidia or mycelia. Published literature characterize *Trichoderma harzianum* strain T-39 by colony and structural morphology, and by intraspecific DNA primers. Additional data are likely to be required for more extensive use patterns.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the relevant available scientific data and other information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Results of the following studies support the lack of toxicity/pathogenicity of the Technical Grade Active Ingredient (TGAI), *Trichoderma harzianum*: acute oral, acute dermal, and the primary dermal irritation. The microbial pesticide was classified acute Toxicity Category III for these health effects.

The two acute eye irritation studies indicate a potential for the TGAI to cause severe eye irritation, placing the Technical Grade Active Ingredient in acute Toxicity Category I. However, another eye irritation study in which the test material was the End-use Product (EP), Trichodex, indicates the EP is mildly irritating or in the acute Toxicity Category III. This categorization is acceptable for labeling of the EP.

While the acute pulmonary study indicated that the TGAI *Trichoderma harzianum* did not replicate in the rat body, the reported data did not demonstrate a clear clearance pattern from the lungs. Based on this study and because the predominant inert ingredient is a known inhalation hazard, the microbial was classified as an acute Toxicity Category II pesticide for acute inhalation effects.

III. Aggregate Exposures and Risk

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures of consumers and major identifiable subgroups of consumers from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure and Risk

Dietary exposure to the microbial pesticide is likely to occur. The lack of acute oral toxicity/pathogenicity, and the ubiquitous nature of the microbial, support the establishment of an exemption from the requirement of a temporary tolerance for this active ingredient.

1. *Food*. The microbial pesticide can be easily removed from foods by washing, peeling, cooking and processing. For this EUP, strawberry, wine grape and table grape are to be treated in small areas in seven states AZ, CA. FL, NY, OH, OR, and WA. Consequently, dietary exposure to the microbial and the risk posed by ingestion of foods treated with the microbial pesticide, are likely to be minimal for adults, infants and children by the oral route.

2. *Drinking water exposure*. Oral exposure, at very low levels, may occur from ingestion of drinking water. However, the experimental permit allows use of this pesticide on a small area in one state on three crops, thus limiting potential exposure to drinking water. Even if negligible exposure should occur, the Agency concludes that such exposure would present no risk due to the lack of toxicity and the ubiquitous nature of the microbe.

B. Other Non-Occupational Exposure

The experimental use sites for *Trichoderma harzianum* strain T-39 are strawberry, wine grape and table grape for control of Botrytis by displacement. Therefore, exposure and risk to adults, infants and children via treated lawns or recreational areas are not likely if the pesticide is used as labeled.

1. *Dermal exposure*. The experimental use permit allows limited use of the pesticide in small areas in seven states. Workers are most likely to be dermally exposed during treatment of strawberry, wine grape and table grape. Because the pesticide is placed in Acute Toxicity Category III for dermal effects and the experimental use of the pesticide is limited, the exposure and risk to workers is likely to be minimal. Appropriate Personal Protective Equipment have been recommended by the Agency to mitigate against potential dermal exposure to pesticide handlers.

2. *Inhalation exposure*. The pesticide is considered an Acute Toxicity Category II microbial pesticide on the basis of inhalation studies. Adequate Personal Protective Equipment, including a dust-mist filtering respirator with NIOSH/MSHA prefix TC–21C, or equivalent, such as N–95, R–95 or P–95 respirator, and a Restricted-Entry Interval of 12 hours are required to mitigate against potential exposure and risk posed by the use of the pesticide during the experimental field trials.

IV. Cumulative Exposure to Substances with Common Mechanisms of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' There are other species and strains of *Trichoderma* registered. As discussed under Product Chemistry, the Agency has received information to distinguish strain T-39 from other registered strains. It is not clear to the Agency whether the registered strains share a common mechanism of toxicity, or any mechanism of toxicity with strain T-39.

V. Safety Factors

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre-and-post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when *Trichoderma harzianum* strain T-39 is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply.

VI. Infants and Children

The pesticide is to be applied to strawberry, wine grape and table grape to small areas in seven states as previously described. Because of this limited use pattern, and its low toxicity/pathogenicity, there is minimal potential for exposure and risk to infants and children.

VII. Determination of Safety for U.S. Population, Infants and Children

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to *Trichoderma harzianum* strain T-39 from the limited use pattern of this experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

VIII. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

The Agency is requiring standard microbial assays and analytical methods to identify the active ingredient and potential contaminants.

C. Environmental Effects

This final rule also extends the Experimental Use Permit associated with the exemption from the requirement of a temporary tolerance. Data and information have been provided to support the extension of the EUP. The application of this pesticide to the experimental fields is not likely to have adverse effects on avian species, fish and honey bee. These data include two 14–day acute oral avian studies in the mallard duck and bobwhite quail, a 96–hour study for freshwater fish, and a honeybee study. While the studies were not adequate for a section 3(c) 2(b) registration, they are adequate for the limited EUP. Additional data are required for more extensive use patterns.

IX. Conclusions

The Agency has concluded that the experimental use of this pesticide will not pose any adverse health effects to the U.S. population, infants and children, nor to the environment because of the low toxicological profile and the limited use patterns discussed above for this EUP. As a result, EPA establishes an exemption from temporary tolerance requirements pursuant to FFDCA section 408(j)(3) for *Trichoderma harzianum* strain T-39 in/on strawberry, table grape and wine grape. This exemption from the requirement of a temporary tolerance expires November 30, 2000. This rule also concurrently extends the Experimental Use Permit to November 30, 2000.

X. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 16, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

XI. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, as described above, will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket contol number (OPP–300698). No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

XII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the requirement of a temporary tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require and prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from

Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In additions, since tolerance exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

XIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 26, 1998.

Kathleen D. Knox,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1201, is added to subpart D to read as follows:

§180.1201 Trichoderma harzianum strain T-39; exemption from the requirement of a temporary tolerance.

Trichoderma harzianum strain T-39 is exempted from the requirement of a temporary tolerance in/on table grapes, wine grapes and strawberries treated in accordance with the Experimental Use Permit 11678–EUP–1. This exemption from the requirement of a tolerance will expire on November 30, 2000.

[FR Doc. 98–24839 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300707; FRL–6026–4]

RIN 2070-AB78

Desmedipham; Extension of Tolerances for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends time-limited tolerances for residues of the herbicide desmedipham in or on red beet roots at 0.2 part per million (ppm) and red beet tops at 15 ppm for an additional 1-year period, to August 31, 1999. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on red beets. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective September 16, 1998. Objections and requests for hearings must be

received by EPA, on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300707], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300707], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 267, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308–9362; e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of August 29, 1997 (62 FR 45741) (FRL–5738–5), which announced that on its own initiative and under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established time-limited tolerances for the residues of desmedipham in or on red beet roots at 0.2 ppm and red beet tops at 15 ppm, with an expiration date of August 31, 1998. EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of desmedipham on red beets for this year growing season due to the continued non-routine situation for red beet growers in New York; the voluntary cancellation of diethatyl-ethyl in 1993 has left growers with no registered alternatives which provide adequate or dependable weed control. Significant economic losses are expected without the requested section 18 use of desmedipham. After having reviewed the submission, EPA concurs that emergency conditions exist for this state. EPA has authorized under FIFRA section 18 the use of desmedipham on red beets for control of broadleaf weeds in red beets.

EPA assessed the potential risks presented by residues of desmedipham in or on red beet roots and tops. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of August 29, 1997 (62 FR 45741). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended for an additional 1-year period. Although these tolerances will expire and are revoked on August 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on red beet roots and red beet tops after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 16, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are

received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300707]. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule extends time-limited tolerances that were previously established by EPA under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, this final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

Since this extension of existing time-limited tolerances does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. house of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: August 21, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.353, by revising the table in paragraph (b) to read as follows:

§ 180.353 Desmedipham; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
Red beet roots ..	0.2	8/31/99
Red beet tops ...	15	8/31/99

* * * * *

[FR Doc. 98–24844 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300705; FRL–6025–1]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of myclobutanil in or on artichokes, asparagus, and peppers (bell and non-bell). This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on artichokes, asparagus, and peppers (bell and non-bell) in California (all three commodities), Michigan (asparagus) and New Mexico (peppers). This regulation establishes a maximum permissible level for residues of myclobutanil in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on July 31, 2000.

DATES: This regulation is effective September 16, 1998. Objections and requests for hearings must be received by EPA on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300705], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300705], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300705]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the fungicide myclobutanil, in or on artichokes at 1.0 parts per million (ppm), asparagus at 0.02 ppm, and on peppers (bell and non-bell) at 1.0 ppm. These tolerances will expire and are revoked on July 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does

not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Use of Myclobutanil on Artichokes, Asparagus, and Peppers (Bell and Non-bell), and FFDCA Tolerances

The state of California requested specific exemptions for the use of myclobutanil on artichokes to control powdery mildew, on asparagus to control asparagus rust, and bell and non-bell peppers to control powdery mildew. Michigan requested a specific exemption for use of myclobutanil on asparagus to control asparagus rust. New Mexico requested a specific exemption for the use of myclobutanil on bell and non-bell peppers to control powdery mildew.

EPA has authorized under FIFRA section 18 the use of myclobutanil on artichoke to control powdery mildew in California, on asparagus to control asparagus rust in California and Michigan, and on peppers (bell and non-bell) for control of powdery mildew in California and New Mexico. After having reviewed these submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of myclobutanil in or on artichoke, asparagus, and bell and non-bell peppers. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on July 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on artichoke, asparagus, and peppers (bell and non-bell) after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether myclobutanil meets EPA's registration requirements for use on artichoke, asparagus, or on bell and non-bell peppers or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of myclobutanil by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than those already detailed within this document to use this pesticide on these crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for myclobutanil, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of myclobutanil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for the combined residues of myclobutanil on artichokes at 1.0 ppm, asparagus at 0.02 ppm, and peppers (bell and non-bell) at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by myclobutanil are discussed below.

1. *Acute toxicity*. None. For acute dietary risk, EPA has not identified an acute dietary endpoint.

2. *Short - and intermediate - term toxicity.* For short-term dermal Margin of Exposure (MOE) calculations, the Agency used the systemic NOEL of 100 mg/kg/day from a 21–day dermal toxicity study in rats. This dose was the highest tested in the study. The Agency did not identify an inhalation endpoint.

For intermediate-term MOE calculations, the Agency used the NOEL of 10 miligrams/kilograms/day (mg/kg/day) from a 2–generation reproductive toxicity study in rats. At the Lowest Effect Level (LEL) of 50 mg/kg/day, there were decreases in pup body weight, an increased incidence in the number of stillborns, and atrophy of the prostate and testes.

3. *Chronic toxicity*. EPA has established the RfD for myclobutanil at 0.025 mg/kg/day. This RfD is based on a chronic feeding study in rats using a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. At the Lowest Observed Effect Level (LOEL) of 9.9 mg/kg/day there was testicular atrophy.

4. *Carcinogenicity*. Myclobutanil has been classified as a Group E chemical (no evidence of carcinogenicity for humans) by the Agency.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.443) for the combined residues of myclobutanil alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile plus its alcohol metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on a variety of raw agricultural commodities at levels ranging from 25.0 ppm in raisin waste to 0.02 ppm in cottonseed. Tolerances have also been established (40 CFR 180.443(b)) for the combined residues of myclobutanil plus its alcohol metabolite

(free and bound) and diol metabolite alpha-(4-chlorophenyl)-alpha-(3,4-dihydroxybutyl)-1*H*-1,2,4-triazole-1-propanenitrile, in meat, milk, poultry and eggs, at levels ranging from 0.02 ppm to 1.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from myclobutanil as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made somewhat conservative assumptions -- with the exception of bananas, all commodities having myclobutanil tolerances will contain myclobutanil and metabolite residues and those residues will be at the level of the established tolerance -- which results in an overestimate of human dietary exposure. For bananas an anticipated residue estimate was used. Percent crop-treated estimates were utilized for selected commodities included in the assessment. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment.

The existing myclobutanil tolerances (published, pending, and including the necessary section 18 tolerances) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Population Subgroup	ARC_{food} (mg/kg/day)	%Rfd
U.S. Population (48 states)	0.004283	17%
Nursing Infants (<1 year old)	0.006365	25%
Non-Nursing Infants (<1 year old)	0.018836	75%
Children (1-6 years old)	0.011508	46%
Children (7-12 years old)	0.006924	28%
Northeast Region	0.004573	18%
Western Region	0.004880	19%
Hispanics	0.005066	20%
Non-Hispanic Others	0.004443	18%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the Rfd occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water. Chronic exposure and risk* Based on information available to EPA, myclobutanil is persistent and not considered mobile in soils with the exception of sandy soils. Data are not available for its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile. There is no established Maximum Contaminant Level for residues of myclobutanil in drinking water. No Health Advisory Levels for myclobutanil in drinking water have been established. The ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, September 1992) has no information concerning myclobutanil.

EPA has estimated ground and surface water concentrations for myclobutanil based on the label rate of 0.65 lbs active ingredient (a.i.)/acre and assuming 15 applications per season. (The water numbers were based on turf.) The surface water numbers are based on the results of GENEEC model run. The ground water numbers are based on a screening tool, SCI-GROW, which tends to overestimate the true concentrations in the environment.

Surface water EEC based on the results of a GENEEC model run

Acute = 145.96 ppb (0.14596 ppm or mg/L)(maximum initial concentration)

Chronic = 118.6 ppb (0.1186 ppm or mg/L)(average 56-day concentration)

EPA divides the 90/56-day GENEEC value by 3 to obtain a value for chronic risk assessment calculations. Therefore, the surface water value for use in the chronic risk assessment would be 0.04 ppm or mg/L.

Ground water EEC (SCI-GROW estimate)

3.6 ppb (0.0036 ppm or mg/L) (use for both acute and chronic)

Chronic exposure from surface water is calculated below. Chronic exposure from ground water is lower.

EPA has calculated drinking water levels of concern (DWLOCs) for chronic (non-cancer) exposure to be 0.7 ppm for U.S. population, 0.6 ppm for Hispanics, and 0.06 ppm for non-nursing infants (<1 year old). To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to myclobutanil in drinking water.

The estimated average concentration of myclobutanil in surface water is 0.04 ppm. Chronic concentrations in ground water are not expected to be higher than the acute concentrations. The estimated average concentrations of myclobutanil in surface water are less than EPA's levels of concern for myclobutanil in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account the present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of myclobutanil in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

EPA bases this determination on a comparison of estimated concentrations of myclobutanil in surface waters and ground waters to back-calculated ''levels of concern'' for myclobutanil in drinking water. These levels of concern in drinking water were determined after EPA has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of myclobutanil in surface waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of myclobutanil on drinking water as a part of the aggregate risk assessment process.

3. *From non-dietary exposure.* Myclobutanil is currently registered for outdoor residential and greenhouse use on annuals and perennials, turf, shrubs, trees, and flowers. EPA has determined that these uses do not constitute a chronic exposure scenario, but may constitute a short- to intermediate-term exposure scenario (Note: the intermediate-term potential exposure would come from Post-application (dermal for adult; and dermal + ingestion of soil only, due to the persistence of the pesticide in soil, for toddlers). Other intermediate-term exposure scenarios are unlikely as dissipation is strongly influenced by the growth of the grass which needs weekly mowing (more frequently in spring) and most dissipation studies on lawns show considerable tailing off of residues by day 3 or 4; thus, the expectation of significant residues is very unlikely.

4. *Homeowner-use Products.* End-use products containing the active ingredient, myclobutanil, are marketed for homeowner use. The homeowner use with the greatest potential for exposure takes the form of small scale lawn application (other additional

application uses are on roses, flowers, ornamental shrubs and trees) of a soluble concentrate with a hose-end, backpack, or trigger bottle sprayer. Application of these products is recommended at two week intervals. Short-term (and not intermediate-term exposures, because of the amount of time it takes to mix, load, and apply this product) exposure is considered only. Short-term exposure, pre- and during application, will be considered an aggregate potential exposure: a summation of this exposure will include exposure levels for: the mixer + loader + applicator + Post-application on day zero (day of application). Short- and intermediate-term exposure will be considered during post-application (Note: Intermediate-term exposure is addressed only during post-application scenarios).

5. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether myclobutanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, myclobutanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that myclobutanil has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Chronic aggregate exposure and risk.* Using the partially refined exposure assumptions described above, EPA has concluded that aggregate exposure (food, water, and residential) to myclobutanil will not exceed EPA's level of concern. For the U.S. population, 17% of the RfD is occupied by dietary (food) exposure. The estimated average concentrations of myclobutanil in surface and ground water are less than EPA's levels of concern for myclobutanil in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of myclobutanil in drinking water do not contribute significantly to the aggregate chronic human health risk at the present time considering the present uses and uses proposed in this action. EPA has determined that the outdoor registered uses of myclobutanil would not fall under a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to myclobutanil residues.

2. *Short- and intermediate-term risk.* The short-term NOEL for dermal exposure is based on a dermal exposure toxicity study. Since the NOEL is based on a dermal study, oral exposures generally cannot be used directly to calculate a short-term aggregate exposure. However, because EPA determined that a dermal absorption factor of 100% should be used for risk assessment, oral exposures need not be multiplied by a modifying factor (converted to dermal equivalents) so that they can be compared to the dermal endpoint.

The chronic dietary exposure and calculated dietary MOE for the U.S. Population is as follows: MOE= 23,000, based on ARC of 0.004283 mg/kg/day.

The intermediate-term exposure scenarios and calculated MOE for the U.S.Population is as follows: MOE= 2,300, based on ARC of 0.004283 mg/kg/day.

There is a potential for short-term exposure from drinking water. However, as estimated average concentrations of myclobutanil in surface and ground water are less than EPA's levels of concern for drinking water as a contribution to chronic aggregate and acute aggregate exposures, contribution to short-term exposure should not exceed EPA's levels of concern either.

EPA concludes that short-term aggregate MOEs for adults are acceptable considering the default assumptions used in the derivation of exposure estimates and the fact that a LOEL was not identified in the 28-day rat dermal toxicity study the highest dose tested (HDT) was the NOEL in this study used to determine the MOE. Chemical-specific dissipation data and residential use/usage information are required to further refine these post-application exposure estimates.

D. Aggregate Cancer Risk for U.S. Population

Myclobutanil was classified by the Agency as a Group E chemical (no evidence of carcinogenicity for humans). Thus, a cancer risk assessment was not conducted.

E. Endocrine Disruptor Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At

that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Based on the adverse testicular findings, and increase in the number of stillborns, and a decrease in pup weight gain during lactation, in the chronic toxicity and reproduction studies in rats, myclobutanil should be considered as a candidate for evaluation as an endocrine disruptor.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* —i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental study in rats, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (fetal) NOEL was 93.8 mg/kg/day based on incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LOEL of 200 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LOEL of 50 mg/kg/day. The reproductive (pup) NOEL was 10 mg/kg/day, based on the increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for myclobutanil is complete with respect to current toxicological data requirements. Based on the developmental and reproductive toxicity studies discussed above, for myclobutanil there does not appear to be an extra sensitivity for pre- or post-natal effects.

v. *Conclusion*. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an factor is not needed to protect the safety of infants and children.

2. *Chronic risk.* Using the partially-refined exposure assumptions described above, EPA has concluded that aggregate exposure to myclobutanil from food ranges from 25% of the RfD for nursing infants (<1 year old), up to 75% for non-nursing infants (<1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to myclobutanil in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to myclobutanil residues.

3. *Short- or intermediate-term risk.* The short-term NOEL for dermal exposure is based on a dermal exposure toxicity study. Since the NOEL is based on a dermal study, oral exposures generally cannot be used directly to calculate a short-term aggregate exposure. However, because EPA determined that a dermal absorption factor of 100% should be used for risk assessment, oral exposures need not be multiplied by a modifying factor (converted to dermal equivalents) so that they can be compared to the dermal endpoint.

The chronic dietary exposure and calculated dietary MOE for infants (non-nursing, < 1 year old) is 5,300, based on ARC of 0.018836 mg/kg/day.

The dermal residential exposure is 0.85 mg/kg/day (reentry). The calculated dietary MOE for non-nursing infants (<1 year old) is 5,300.

For the short-term aggregate risk of the most highly exposed subgroup (non-nursing infants (<1 year old)), the calculated MOE is 120. There is a potential for short-term exposure from drinking water. However, as estimated average concentrations of myclobutanil in surface and ground water are less than EPA's levels of concern for drinking water as a contribution to chronic aggregate and acute aggregate exposures, contribution to short-term exposure should not exceed EPA's levels of concern either. EPA concludes that short-term aggregate MOEs for non-nursing infants (<1 year old) are acceptable.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residue of concern is myclobutanil plus its alcohol metabolite (free and bound), as specified in 40 CFR 180.443(a).

B. Analytical Enforcement Methodology

An adequate enforcement method is available to enforce the established tolerances. Quantitation is by Gas Liquid Chromatography (GLC) using an Nitrogen/Phosphorus detector for myclobu-tanil and an Electron Capture detector (Ni^{63}) for residues measured as the alcohol metabolite.

C. Magnitude of Residues

Residues of myclobutanil and its alcohol metabolite are not expected to exceed 1.0 ppm in/on artichoke, 0.02 ppm in/on asparagus, and 1.0 ppm in/on peppers (bell and non-bell), as a result of these section 18 uses. Secondary residues are not expected in animal commodities as no feedstuffs are associated with these section 18 uses. Meat/ milk/poultry/ egg tolerances have been established as a result of other myclobutanil uses.

D. International Residue Limits

There are no Codex, Canadian or Mexican residue limits established for myclobutanil and its metabolites on the commodities included in these section 18 requests. Thus, harmonization is not an issue for these section 18 actions.

E. Rotational Crop Restrictions.

Information concerning the likelihood of residues in rotational crops is not currently available for myclobutanil, although such data is expected to be submitted to EPA shortly. Until EPA has reviewed and approved such data, the Agency has required that the following restriction should be added to the label for approved section 18 uses: Rally treated fields can be rotated at any time to crops which are included on the Rally label. For crops not listed on the registered label, do not plant new crops on treated fields for these periods: leafy vegetables, small grains -- 120 days root vegetables, all other crops -- 210 days.

VI. Conclusion

Therefore, the tolerance is established for combined residues of myclobutanil in artichoke at 1.0 ppm, asparagus at 0.02 ppm, and bell and non-bell peppers at 1.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 16, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300705] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition,

Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 26, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority : 21 U.S.C. 346a and 371.

2. In section 180.443, by adding new entries for artichokes, asparagus, and peppers (bell and non-bell) in alphabetical order to the table in paragraph (b), to read as follows:

§ 180.443 Myclobutanil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Artichoke	1.0	7/31/00
Asparagus	0.02	7/31/00
*	*	*
Peppers (bell and non-bell)	1.0	7/31/00
*	*	*

* * * * *

[FR Doc. 98–24845 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300699; FRL–6022–5]

RIN 2070–AB78

Propyzamide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propyzamide (pronamide) and its metabolites containing the 3,5-dichlorobenzoyl moiety (calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on cranberries, grass hay, and grass forage. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal

Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cranberries, and on grass grown for seed. This regulation establishes maximum permissible levels for residues of propyzamide in these food and feed commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on December 31, 1999.

DATES: This regulation is effective September 16, 1998. Objections and requests for hearings must be received by EPA on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300699], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300699], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300699]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: Telephone numbers and e-mail addresses: For propyzamide on cranberries: Andrew Ertman, (703) 308–9367, e-mail: ertman.andrew@epamail.epa.gov; for propyzamide on grass grown for seed: Andrea Beard (703) 308–9356, e-mail: beard.andrea@epamail.epa.gov. Office location (both): Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. By mail (both): Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the herbicide propyzamide (pronamide) and its metabolites, in or on cranberries at 0.05 part per million (ppm), and in or on grass forage at 1 ppm and grass hay at 0.5 ppm. These tolerances will expire and are revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Propyzamide (Pronamide) and FFDCA Tolerances

Propyzamide on Cranberries: Dodder is a serious and devastating pest in commercial cranberry production as well as many other agricultural crops. It is an obligate shoot parasite that, in order to survive, must make a successful attachment to a host plant. The body of the organism consists of thin, yellow, twining stems that produce small clusters of white flowers and can form a dense mat of ''spaghetti-like'' stems on top of infected plants. Dodder is prolific in its seed production, and produces seeds in capsules that are contained in large air spaces and are thus very buoyant. With the widespread adoption of water harvesting, dodder infestations have become practically ubiquitous in the Massachusetts production area. The detrimental impact of dodder infestations on cranberry yields have been reported widely in scientific journals, extension publications and internal memorandum. Yield losses can range from 12% in slight infestations up to 100% in severe infestations. Currently registered herbicides have not been totally effective, leading to a steady increase in dodder infestations.

Propyzamide on Grasses grown for seed: Because of cancellation of several herbicide uses in recent years, a shift in weed populations and the development of resistance, plus restrictions imposed on open field burning, grass growers are no longer able to control weeds adequately with registered materials and cultural methods. The Applicants claim that if weeds are not adequately controlled, growers will incur significant economic losses due to reduced yields, and from losses due to contaminated seed, and replanting of fields that do not meet certification requirements. The Applicant proposed use of propyzamide, in conjunction with several other herbicides, to comprise a comprehensive management system to solve the current weed control problems in grass seed production.

EPA has authorized under FIFRA section 18 the use of propyzamide on cranberries for control of dodder in Massachusetts, and on grasses grown for seed to control grassy weeds in Oregon. After having reviewed the submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of propyzamide in or on cranberries and grass hay and forage. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 1999, under FFDC a section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on cranberries or grass hay or grass forage after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether propyzamide meets EPA's registration requirements for use on cranberries or grasses grown for seed or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of propyzamide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Massachusetts or Oregon to use this pesticide on the specified crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding these emergency exemptions for propyzamide, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The Rfd is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the Rfd (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute'', ''short-term'', ''intermediate term'', and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address

primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue dat a and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (Non-Nursing Infants <1 year old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of propyzamide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of propyzamide (pronamide) and its metabolites containing the 3,5-dichlorobenzoyl moiety (calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) on cranberries at 0.05 ppm, on grass forage at 1.0 ppm, and on grass hay at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by propyzamide are discussed below.

1. *Acute toxicity.* None. For acute dietary risk assessment, EPA has determined, based on the available data, that an acute dietary endpoint was not necessary for purposes of risk assessment.

2. *Short - and intermediate - term toxicity.* EPA has not identified any toxicity endpoints for short- or intermediate-term toxicity, and has determined, based on the data, that these risk assessments are not necessary.

3. *Chronic toxicity.* EPA has established the Reference Dose (RfD) for propyzamide at 0.08 milligrams/kilogram body weight/day (mg/kg bwt/day). The RfD was established based on a 2–year feeding study in rats with a NOEL of 8.46 mg/kg/day and using an uncertainty factor of 100. The Lowest Observed Effect Level (LOEL) of 42.6 mg/kg/day was based on decreased mean body weight and decreased mean body weight gain, increased relative liver weight, increased incidences of hepatic centrilobular hypertrophy, as well as eosinophilic cell alterations and thyroid follicular cell hypertrophy in both males and females. In females there was an increased incidence of ovarian hyperplasia.

4. *Carcinogenicity.* Propyzamide has been classified as a Group B2 (probable human carcinogen) chemical. The decision was based on the finding of two types of tumors in the rat (benign testicular interstitial cell tumors and thyroid follicular cell adenomas), and one type in the mouse (liver carcinomas). The Agency recommended using the Q_1* approach (Q_1* = 0.01540) for purposes of risk assessment.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.317) for the residues of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-

propynyl)benzamide) in or on a variety of raw agricultural commodities at levels ranging from 0.02 ppm in milk to 10 ppm in nongrass animal feeds. Risk assessments were conducted by EPA to assess dietary exposures and risks from propyzamide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. As the Agency did not identify an acute dietary endpoint, no acute risk assessment was conducted.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made partially refined assumptions. For cranberries, the conservative assumptions of tolerance level residues and 100% crop treated were used. Refinements to other commodities included anticipated residues for lettuce, milk, eggs, and most poultry commodities; additionally, percent of crop treated figures were incorporated for small berries, grapes, cherries, stone fruits, pome fruits, lettuce, and artichokes. All other commodities were assumed to be 100% crop treated and to contain tolerance level residues.

The existing propyzamide tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in an Anticipated Residue Contributions (ARCs) that are equivalent to <1% of the RfD for all population subgroups, as shown below:

Population Subgroup	ARC (mg/kg/day)	%RFD
U.S. Population (48 States)	0.000151	0.19
Nursing Infants (<1 year old)	0.000195	0.24
Non-Nursing Infants (<1 year old)	0.000601	0.75
Children (1–6 years old)	0.000354	0.44
Children (7–12 years old)	0.000225	0.28

iii. *Cancer risk*. Propyzamide has been classified as a Group B2 (probable human carcinogen) chemical by the Agency. The decision was based on the finding of two types of tumors in the rat (benign testicular interstitial cell tumors and thyroid follicular cell adenomas), and one type in the mouse (liver carcinomas). The Agency recommended using the Q_1* approach (Q_1*=0.01540(mg/kg/day)$^{-1}$) for purposes of risk assessment. Using the partially refined exposure estimates described above, the cancer risk estimate for the U.S.population is 2.3×10^{-6}. The contribution of propyzamide exposure resulting from this section 18 use has been amortized for 5 years for the purposes of this section 18 only. Although the cancer risk estimate exceeds 1×10^{-6}, this risk analysis assumed all the beef, goat, sheep, and pork commodities contain tolerance level residues. Although the milk, turkey, poultry, and egg commodities were assumed to contain anticipated residues, the percent treated values used were 100. These commodities contribute significantly to the diet. Therefore, if anticipated residues were used for all commodities, and actual percent treated values were used for all these animal commodities, it is expected that the cancer risk estimate from food would fall below 1×10^{-6}.

2. *From drinking water.* Based on information in the Agency's files, propyzamide is persistent and not mobile. There is no established Maximum Contaminant Level for residues of propyzamide in drinking water. A lifetime health advisory level of 0.05 mg/L for propyzamide in drinking water has been established. The Agency utilized GENEEC and SCIGROW computer modeling to estimate pesticide concentrations found in surface and ground waters, respectively, thus providing a reasonable and conservative upper-bound estimate for screening purposes, for use in the human health risk assessment. For surface water, the chronic (average 56–day) value is 8.3 parts per billion (ppb). The groundwater screening concentration is 0.28 ppb.

i. *Acute exposure and risk.* Because no acute dietary endpoint was identified, no acute risk assessment was conducted.

ii. *Chronic exposure and risk.* Chronic drinking water levels of concern (DWLOC) for propyzamide were calculated based on the chronic dietary (food) exposure estimates. A human health DWLOC is the concentration in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that chemical from food, water, and non-occupational (residential) sources. It is current Agency policy that the following subpopulations be addressed when calculating drinking water levels of concern: US population (48 States), Males (13+ years), Females (13+ years), and all infants/children and if other adult populations greater than the U.S. population, the highest of them also. In conducting these calculations, default body weights are used of 70 kg (adult male), 60 kg (adult females), and 10 kg (child); default consumption values of water are used of 2 liters perday for adults and 1 liter per day for children. Using these assumptions and the levels provided by the computer models, given above, the resultant DWLOCs were calculated to be 2,800 ppb for the Overall US population and Males (13–19), 2,400 ppb for Females (13–19 yrs. old), and 790 ppb for the most highly exposed infant/children subpopulation, Non-Nursing Infants (<1 Year Old). These values are substantially higher than the residue estimates calculated. Therefore, chronic exposure to propyzamide residues in drinking water do not exceed the Agency's level of concern.

iii. *Cancer Risk.* The cancer risk estimate (food only) is not likely to exceed the Agency's level of concern. In addition, in the Agency's best scientific judgment, considering the conservative nature of the GENEEC surface water number of 8.3 ppb, EPA does not expect significant additional contribution to cancer risk from exposure to propyzamide in drinking water.

3. *From non-dietary exposure.* Propyzamide is currently registered for use on numerous ornamental plants (including woody shrubs, shade trees, and ornamental turf); there are no indoor uses registered. However, all registered residential uses of propyzamide are currently inactive, and therefore residential uses are not a contributing factor to aggregate risk at this time.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative

effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Propyzamide is a member of the substituted amides class of pesticides. However, EPA does not have, at this time, available data to determine whether propyzamide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, propyzamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propyzamide has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Because no acute dietary endpoint was identified, no acute risk assessment was conducted.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to propyzamide from food will utilize 0.19% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-Nursing Infants, with 0.75% of the RfD utilized, further discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propyzamide in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propyzamide residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Because no endpoint was identified for this type of exposure, EPA did not conduct a risk assessment for short- or intermediate-term exposure.

D. Aggregate Cancer Risk for U.S. Population

As discussed in the previous section, EPA believes that if further refinement of residue and percent crop treated estimates were incorporated in to the risk assessment, the cancer risk from food would fall below 1×10^{-6}. Although the GENEEC drinking water model indicates potential for low residues of propyzamide in water, it is EPA's best scientific judgment that the total aggregate cancer risk presented from propyzamide will not exceed 1×10^{-6}, even if drinking water exposures were to occur at the extremely conservative screening levels estimated. Therefore, EPA concludes that there is a reasonable certainty that no harm in the form of cancer will result from aggregate exposure to propyzamide residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* —i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of propyzamide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental study in rats, there were no maternal (systemic) or developmental (fetal) adverse effects observed at the highest dose tested (160 mg/kg/day).

In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 5 mg/kg/day. The LOEL of 20 mg/kg/day was based on anorexia, vacuolated hepatocytes, and soiled anal area. The developmental (fetal) NOEL was 20 mg/kg/day. The developmental LOEL of 80 mg/kg/day was based on increased number of absorptions and abortions.

iii. *Reproductive toxicity study.* In the 2–generation reproductive toxicity study in rats, the parental (systemic) NOEL was 10 mg/kg/day (200 ppm), based on decreased body weight, and decreased feed consumption at the

LOEL of 75 mg/kg/day (1,500 ppm). The reproductive (pup) NOEL was also 10 mg/kg/day (200 ppm) based on decreased pup weight at the LOEL of 75 mg/kg/day (1,500 ppm).

iv. *Pre- and post-natal sensitivity.* The toxicological database for evaluating pre- and post-natal toxicity for propyzamide is complete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies as well as the 2–generation rat reproductive toxicity study.

v. *Conclusion.* Based upon the available data, outlined above, EPA scientists concluded that reliable data support the conclusion that using the standard 100–fold uncertainty factor will provide adequate protection for infants and children, and that an additional 10–fold uncertainty factor is not warranted. EPA concludes that there is reasonable certainty of safety for infants and children exposed to dietary residues of propyzamide.

2. *Acute risk.* Because no acute dietary endpoint was identified, no acute risk assessment was conducted.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to propyzamide from food will utilize from 0.24% to 0.75% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propyzamide in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propyzamide residues.

4. *Short- or intermediate-term risk.* Because no endpoint was identified for short- or intermediate-term exposure, EPA did not conduct a risk assessment for this type of exposure.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residues of concern are the parent compound and its metabolites containing the 3,5-dichlorobenzoyl moiety, calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide(as specified in 40 CFR 180.317) .

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography using electron capture detection) is available to enforce the tolerance expression. This method is published in PAM II, as method I.

C. Magnitude of Residues

Residues of propyzamide and its regulated metabolites are not expected to exceed 0.05 ppm in/on cranberries, 0.5 ppm in/on grass hay, and 1 ppm in/on grass forage, as a result of these section 18 uses. Secondary residues in animal commodities are not expected from cranberries, and secondary residues resulting form the grass use are not expected to exceed established tolerances.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits for propyzamide on cranberries or grass commodities, so harmonization is not an issue for these section 18 uses.

E. Rotational Crop Restrictions

Cranberries are not a rotated crop, and thus rotational crop restrictions are not applicable. Fields in which certified grass seed is grown are not normally rotated to other crops, and rotational crop restrictions are not required for this use.

VI. Conclusion

Therefore, the tolerances are established for combined residues of propyzamide in/on cranberries at 0.05 ppm, grass hay at 0.5 ppm, and grass forage at 1 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 16, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300699] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58–3, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In addition, since these tolerances and exemptions that are established under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 26, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In §180.317, by revising the heading; by adding a heading to paragraph (a) and revising the introductory text; by designating the current paragraph (b) as (c); by adding a new paragraph (b); by revising the

introductory text of newly designated (c); and by adding and reserving paragraph (d) to read as follows:

§ 180.317 Propyzamide; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on the following raw agricultural commodities:

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of propyzamide, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Cranberries	0.05	12/31/99
Grass, forage	1.0	12/31/99
Grass, hay	0.5	12/31/99

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for the combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on the following raw agricultural commodities:

* * * * *

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 98–24846 Filed 9–15–98; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–138, RM–8855, 8856, 8857, 8858, 8872; FCC 98–175]

Main Studio and Public Inspection File of Broadcast Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this *Report and Order* (''R&O''), the Commission adopts amendments to its rules governing main studio and local public inspection file requirements for broadcast licensees. The Commission relaxes the standard governing the location of the main studio to allow a station to locate within the principal community contour of any station licensed to the community of license, and requires the local public inspection file to be located at the broadcast station's main studio, wherever located. The Commission also amended the public inspection file rules to streamline the contents of the public inspection file. For additional information, *see* Supplementary Information.

EFFECTIVE DATE: These rules contain information collection requirements that are not effective until approved by the Office of Management and Budget. FCC will publish a document in the **Federal Register** announcing the effective date of this document.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Room 222, Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 234, 1919 M Street, NW., Washington, DC 20554, or via the Internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley or Kim Matthews Mass Media Bureau, (202) 418–2130. For additional information concerning the information collections contained in this R&O contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 97–138, adopted July 27, 1998 and released August 11, 1998. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC, 20036, (202) 857–3800.

Synopsis of Report and Order on Main Studio and Public Inspection File

I. Introduction

1. With this *Report and Order,* we amend our rules regarding the main studio and local public inspection file for broadcast stations. In the *Notice of Proposed Rule Making,* 62 FR 32061 (June 12, 1997), we proposed that modification of these rules could serve the public interest. We here conclude that it is possible to grant broadcast licensees additional flexibility in locating their main studios, together with their public files, and adhere to the original purpose underlying these rules: to maintain reasonable accessibility of station facilities, personnel and information to members of the station's community of license, which enables the residents of the community to monitor a station's performance, and encourages a continuing dialogue between the station and its community. In this way, a station is better integrated into the activities of the community and can be more responsive to local community needs in its programming. In order to facilitate this interaction, this *R&O* also amends Sections 73.3526 and 73.3527 of our rules to clarify and update the required contents of the public inspection files. The actions we take today are consistent with our ongoing effort to ensure that our rules continue to serve the public interest without imposing unnecessary regulatory burdens. These modifications in no way alter the obligation of each broadcast licensee to serve the needs and interests of its community.

II. Main Studio Rule

2. *Discussion.* In the *NPRM* in this proceeding, we set forth two goals in determining whether to modify the main studio rule. Our first goal is to strike an appropriate balance between ensuring that the public has reasonable access to each station's main studio and public file and minimizing regulatory burdens on licensees. Our second goal is to adopt clear rules that are easy to administer and understand. In the *NPRM,* sought comment on the option of permitting a station to locate its main studio anywhere in the principal community contour of any station licensed to the same community, or

within a set distance from the community center, whichever it chooses.

3. The *R&O* adopts this option. Specifically, we will allow a station to locate its main studio at any location that is within either the principal community contour of any station, of any service, licensed to its community of license or 25 miles from the reference coordinates of the center of its community of license, whichever it chooses. This approach fulfills our stated goals. By establishing a clear, bright line test for determining location of the main studio, it is clear and easy to administer. It also lessens regulatory burdens. It expands the area in which most licensees may locate their main studios while maintaining a close connection to the community. The contour aspect increases the area in which licensees in communities with multiple stations will be able to choose location, putting all licensees in a community on equal footing, and the mileage aspect increases the area for smaller radio stations, particularly those providing the sole local service in a community. Although this expansion is not limited to co-owned stations, the increased flexibility it provides should allow many more multi-station licensees to combine the resources of their jointly-owned stations, which can allow them to better serve the public. Revising the rule to permit greater co-location of main studios should also reduce the number of waiver requests we have received from licensees in the past, which will reduce the burden on both licensees and the Commission. We note that the action we take today will not affect any stations operating pursuant to a waiver of these rules, particularly licensees of noncommercial educational stations operating their stations as satellites of a main station which historically have been given distinct treatment from commercial stations. Absent a waiver, however, the rules apply equally to commercial and noncommercial stations.

4. At the same time, the standard we are adopting places the main studio in a reasonably accessible location to the community of license. The amended rule maintains broadcasters' obligations under Section 307(b) to provide service to their communities of license by continuing the main studio's connection to the community of license. Our relaxation of the main studio location requirement takes into account the evidence in the record that more people use remote rather than face-to-face means of communication for routine contact with their local stations, and that permitting stations greater flexibility in locating their main studios should not unduly burden the public.

5. Our adoption of a 25-mile permissible range as an alternative option for the licensee is based on a number of factors. First, the 25-mile standard reflects an approximation of the weighted average of the principal community contour radii of FM radio and TV stations (actual weighted average: 23.08 miles). AM radio station contours, based on frequency, power, radiation and ground conductivity, and conceivably quite large, were not taken into account because they vary very significantly from station to station. Second, a 25-mile radius from city center gives stations a 50-mile diameter (1962.5 square miles) within which to locate the main studio. With this standard, citizens at the opposite end of the community would not be expected to have to travel more than 50 miles to reach the studio, which we believe is a reasonably accessible distance to expect members of the public to travel, given today's modern transportation and good roads.

6. *Alternative proposals.* Some commenters proposed variations to the rule we adopt today, some of which would further relax the rules, while others would be more restrictive. As an initial matter, some commenters suggest that we delete the main studio requirement altogether. We continue to believe that the main studio requirement is necessary to ensure that broadcast stations are reasonably accessible to the communities they serve, which provides important public interest benefits.

7. We also are not persuaded by the alternatives advanced by other commenters because those proposals provide relief to fewer stations and could, in some cases, make the studios less accessible than the rule we adopt today. We are satisfied that use of principal community contours or the mileage standard will give stations ample area within which to locate their main studios. Other commenters suggest that we require location of the main studio within the principal community contours of any mutually overlapping co-owned stations. We believe that this approach would benefit only the licensees of multiple stations, and could place the main studio location well beyond a reasonably accessible location to the station's community of license. Other suggestions include defining the permissible area to locate the main studio by TV Grade B contour, designated market area, Arbitron radio market, metropolitan statistical area, or ''protected service contour,'' i.e., the .5 mV/m contour for AM and 1 mV/m contour for FM. We believe that these suggestions would potentially place the main studio at too distant a location from the community to be considered reasonably accessible.

8. We also decline to adopt the proposal which would more restrictively permit location within any contour of any station licensed to the community, or 25 miles from the community center, whichever is *less.*

9. We also reject another variation, which argues that the Commission should continue to require each station to locate its main studio in the community of license because in-person visits will be deterred by a too distant main studio.

III. Local Public Inspection File Rules

A. Location of the Local Public Inspection File

10. *Background.* The Commission's rules generally require a broadcast station to maintain its local public inspection file at its main studio, when the main studio is located within the station's community of license, or at any accessible place in the community of license (*e.g.*, an attorney's office or local public library) if the station's main studio is located outside the community. As with the main studio rule, reasonable access to the public inspection file serves the important purpose of facilitating citizen monitoring of a station's operations and public interest performance and fostering community involvement with local stations. This in turn helps ensure that stations are responsive to the needs and interests of their local communities.

11. *Discussion.* Based on the proposals and comments before us, we believe that it is in the public interest to amend the public file rules, §§ 73.3526(d) and 73.3527(d) of our rules, to provide that the licensee of a station locate its public file at its main studio, wherever located. In addition, the rules we adopt today provide that an applicant for a new station or change of community locate its public inspection file in the proposed community of license or at its proposed main studio. We also are giving licensees the option of maintaining all or part of their public file in a computer database rather than in paper files, and are encouraging licensees who chose this option to post their ''electronic'' public files on any World Wide Web sites they maintain on the internet.

12. We believe that having a licensee maintain its public file at its main studio will fulfill our stated goals. It takes into account the fact that many members of the public contact stations

by telephone, and the accommodation we set forth below will facilitate access to the public file by permitting individuals to call a station and request that it mail portions of the file to the caller's home or office. As several commenters point out, the main studio is the most logical and likely place for the public to expect to find a station's public inspection file. It is listed in the telephone book, and is usually well marked by commercial signage. These factors are likely to increase the convenience to the public in some cases, and could also facilitate public involvement at the station. The public would also be better served if the file is maintained and stored under the direct control of the station. Not only would there be greater assurance that the file is kept up-to-date and in proper order, but also the licensee would be able to provide assistance to those researching the public file, if necessary. As some commenters point out, collocating the public file and main studio will reduce the burdens on licensees who previously were required to maintain an off-premises public file in the community of license because their main studios are outside the city limits of the community of license. Moreover, we note that co-location of the main studio and public file will aid same-market, multiple-station owners by allowing them to channel their resources in ways that would better serve the public.

13. *Accommodation.* We will require stations to make available, by mail upon telephone request, photocopies of documents in the public file, including our revised version of ''The Public and Broadcasting'' (as drafted by the FCC staff; *see infra*) which shall also be placed on the FCC's internet site. This manual will generally describe broadcasters' public file obligations, and how the public can help monitor licensee performance. The station may require the person requesting the copies to pay the reasonable cost of photocopying and the station will pay postage. To facilitate requests for public file documents over the telephone, we will require stations to provide callers, if they wish to receive one, a copy of the new edition of ''The Public and Broadcasting'' free of charge. This description will assist callers in identifying documents they may ask to be sent to them by mail. We will require licensees to assist callers in this process and answer questions they may have about the actual contents of the station's public file. For example, stations, if asked, should describe to a caller the number of pages and time periods covered by a particular ownership report or children's television programming report, or the types of applications actually maintained in the station's public file and the dates they were filed with the FCC. We also encourage stations to place the descriptions of their public files on any Internet home page that they maintain. We believe that this accommodation for the public should ensure that public file materials continue to be reasonably accessible to all members of the public. The revised ''The Public and Broadcasting'' should facilitate this access by educating the public about the contents of the file.

14. We reject the other accommodations mentioned in the *NPRM* and proposed by commenters. In addition to the accommodations raised in the *NPRM*, accommodations supported by commenters include courier, fax or e-mail delivery, toll-free telephone service, or requiring stations to make their studio available at non-business hours by appointment. Some commenters suggest that the actual method of provision of public file access be voluntary or left to licensee discretion, but within a set period of time from the time of the request. We have considered all of the alternate suggestions and have determined that the accommodation we require in this rule fulfills our stated goals of balancing public access with regulatory burden and ease and clarity of administration. As noted, toll-free telephone service is already required. We believe that requiring stations to provide transportation to requesters, to transport the public file to them or open the main studio during non-business hours would be unnecessarily burdensome to station owners. Finally, Noncommercial Educational Licensees request that we place a limit on the number of requests to avoid harassing requests. We will not adopt such a limit; there is no evidence in the record that public requests for information are made in bad faith to any significant extent, or that stations are being overwhelmed by such requests. A licensee, may, of course, seek a waiver or special relief from the Commission in the event such circumstances arise.

15. Several commenters specifically disagree with making any accommodation, including the one we have adopted. Most cite the undue burden on broadcasters, discouragement from locating outside the community, and the ease with which the accommodations could be abused. One specifically notes that allowing requests by phone rather than in-person could encourage frivolous requests and that allowing requests without in-person review by the requestor will burden licensees because the requestor will not be able to make an informed request without looking through the file, and stations will have to interpret these vague requests and become researchers to determine exactly what the requestor needs. We believe that the rules we adopt today address these concerns. First, a requestor is entitled to ''The Public and Broadcasting,'' which should provide adequate guidance to make an intelligent request for information. In addition, the rules regarding the public file's contents in their revised form will be much easier to understand and administer for both licensees and the public seeking information. Finally, we expect that requiring a person seeking documents from a station's public file to pay the reasonable expenses of photocopying should reduce the possibility for abusive and frivolous requests.

B. Contents of the Local Public Inspection File

16. *Background.* In the *NPRM*, we sought comment on updating our requirements regarding the materials that a station must place in its public inspection file. Currently, both commercial and noncommercial broadcast licensees must maintain a local public inspection file containing copies of certain applications and related materials filed by the station with the FCC, ownership reports, employment reports, and a list of programs aired by the station during the previous three months that provided its most significant treatment of community issues (the ''issues/programs list''). Commercial broadcast licensees must also retain written comments and suggestions received from the public regarding operation of their stations. In addition, broadcast licensees must maintain a separate public file concerning requests by political candidates for broadcast time on the station, and commercial television licensees must maintain a file containing information regarding the educational and informational programming they air for children.

17. *Updates to the Rules.* In the *NPRM*, we proposed the following specific amendments to update and clarify the public inspection file rules:

(a) We proposed to delete the requirement that licensees maintain in their public file a copy of the 1974 manual entitled ''The Public and Broadcasting,'' noting that this manual is long out-of-date.

(b) We proposed to delete the reference in § 73.3526(a)(11) of our rules regarding the maintenance of reports

required under our financial interest and syndication rules, which have been repealed.

(c) We stated that we will correct the cross-reference in the public inspection file rules to the rule section governing a licensee's political file.

(d) We proposed to delete the note set forth under §§ 73.3526(a)(1) and 73.3527(a)(1) of the public inspection file rules exempting from the rules certain applications filed on or before May 13, 1965. We noted that, even without the exemption, the retention periods for maintaining such applications have long since expired.

18. We will adopt the three specific proposals, described as (b), (c), and (d) above, to amend our public inspection file rules. No commenters objected to these revisions, and they will serve to clarify and make current licensees' obligations under these rules. With respect to our first proposal regarding the 1974 manual ''The Public and Broadcasting,'' we will no longer require licensees to maintain this out-of-date document. Rather, the FCC Staff will update this manual and the new manual will describe our new requirements regarding the contents of the public file, and discuss ways in which the public can help monitor licensee performance. We believe that this updated manual will provide a useful description of the documents that are available for public inspection, and will facilitate interaction between licensees and their communities that may lead to improved service to the public. The Commission staff will prepare the manual, and issue a Public Notice notifying licensees when it is complete. We expect that the staff will be issuing the new version of this manual in the fourth quarter of this year. The Commission will place the new manual on its World Wide Web site on the internet, where it can be accessed and downloaded by licensees and the public. The address for the Commission's internet home page is: http://www.fcc.gov. We will require all commercial and noncommercial licensees to replace their 1974 manuals with the updated version when it is available.

19. *Assignment of License.* Our current rules provide that after the Commission approves an application for assignment of license and the transaction has been consummated, the assignee is responsible for ensuring that the public file contains all the documents previously required to be maintained in the file by the assignor. We stated in the *NPRM* that we had received a petition for rule making requesting that the Commission amend the public file rule to delete this requirement. The petitioner argued that the proposed change is warranted because the public file need only contain information concerning the *current* licensee or permittee, as the public has no practical use for information regarding the ownership, programming, and EEO practices of a station's prior licensees. The petitioner also contended that a new licensee should not bear the burden of locating documents missing from a prior licensee's public file. We stated our belief that there is merit to these arguments regarding licensee-specific information, but noted that there may be information in the public file relevant to a station's facilities that is not licensee-specific (*e.g.*, engineering material in a modification application filed by the assignor) and therefore should be maintained by the assignee. We invited commenters to address this issue.

20. In the case of an assignment of license, we will continue to require the assignee to retain public file documents obtained from the assignor for the period required by our revised rules. However, we will not hold assignees responsible for correcting any omissions in the file that exist at the time of the assignment. We believe that, on balance, requiring licensees to retain the assignor's public file intact is a minimal burden which is outweighed by the benefit to the public of continued access to these materials for the entire retention period. We are persuaded by those commenters who argued that relatively little effort and expense is required to simply retain public file materials obtained from an assignor, rather than disposing of all or part of those materials. Documents that relate to the operations of a previous licensee can be relevant and useful in the context of a challenge to or investigation of the qualifications of that licensee to hold other FCC authorizations. In view of the large number of station sales in recent years, especially in the radio market, and the longer eight-year license period, it increasingly occurs that a station is assigned to a new owner before the license term is complete. To ensure that the previous owner's record is available for review, we will require that the file inherited from the assignor be retained for the full period specified by our rules.

21. While we will continue to require an assignee to retain records obtained from an assignor, we will not hold licensees strictly liable for omissions created by predecessors. However, we expect parties engaged in the purchase of a station to make a good faith effort to correct deficiencies in the assignor's file that exist at the time of the assignment through the due diligence process typically undertaken by a purchaser of a station. Given the other rule changes we are adopting today, we expect that as a general matter there will be fewer instances where a licensee's public file will be missing required documents, whether at the time of an assignment or any other time. In particular, we are making revisions today both to reduce the number of documents required to be maintained in the public file and to clarify the retention requirements. This should help reduce the number of instances in which the public file is found to be incomplete. Moreover, the revisions we are making today to our rules governing public file location should improve management and maintenance of the file by licensees, further facilitating compliance. We emphasize that all licensees have a duty to comply with our public file rules, and expect that licensees will find this obligation easier to meet in light of the revisions we are making today.

22. *Electronic mail.* We proposed in the *NPRM* to clarify the requirement that ''[a]ll written comments and suggestions received from the public by licensees of commercial AM, FM, and TV broadcast stations regarding operation of their station shall be maintained in the local public inspection file.'' We stated our wish to clarify that such ''written comments and suggestions'' include electronic mail messages transmitted via the internet. We noted that internet ''e-mail'' is an increasingly popular means of communication, and invited comment on this proposed clarification.

23. We will adopt our proposal to clarify that our rules require the retention by licensees of e-mail messages as well as traditional printed communications. We concur with those commenters that expressed the view that there is no fundamental distinction between e-mail and printed letters that would justify treating those forms of communication differently for purposes of this rule. Both means of communication can be used to convey important comments or suggestions regarding programming, and should be treated in a similar fashion. We will give licensees the option of retaining e-mail messages either in a computer or a paper file. Rather than printing out hard copies of these e-mail communications, licensees that choose the computer file option may provide the public upon request with a computer diskette containing copies of the e-mails received by the station, or may make available to the public a computer terminal where these communications may be accessed. In the case of identical

e-mails or letters received from different parties, we will also give licensees the option of retaining, either on paper or in a computer file, a single sample copy of the e-mail or letter as well as list of all parties that sent identical e-mails or letters to the station.

24. For reasons of clarity, rather than retaining our rules governing the retention of letters received by commercial broadcast stations in a separate rule section, § 73.1202, we have moved those rules to § 73.3526, our public file rule section for commercial broadcast stations. The obligation to retain letters received from the public is fundamentally a public file obligation, and should therefore be part of the public file rules themselves.

25. Retention requirements. We also sought comment in the *NPRM* on whether the retention periods for the materials in the public inspection file and political file should be revised to update and clarify those provisions. At a minimum, we proposed to revise those retention periods tied to the broadcast license term to reflect the new license term of eight years. We also proposed to amend the rules to require that all documents required to be retained for the license term be retained not only for the eight-year term but until the grant of the renewal application is final, *i.e.*, no longer subject to reconsideration, review, or appeal either at the FCC or in the courts. In addition, we sought comment on whether any of the public file retention periods can be shortened to reduce regulatory burdens. In particular, we noted that we currently require that certain applications filed with the FCC be retained until ''the expiration of one license term * * * or until grant of the first renewal application of the television or radio broadcast license in question.'' We proposed shortening the required retention period for license assignment and transfer applications and applications for major facilities modifications to the period in which they are pending before the FCC or the courts. We noted that this is the period of time these applications are of particular relevance to the public, and that after this period other public file materials such as ownership reports may provide an alternative source for the information contained in these applications. Finally, we also sought comment on other ways to clarify and streamline our retention period requirements, and on the appropriate retention periods for letters received from the public, annual employment reports, and annual ownership reports.

26. We believe there is significant room for clarification of our public file retention requirements, and agree with those commenters who argue that some of the current rules are unnecessarily complex. We also believe that our public file requirements can be streamlined, either by shortening the retention period where appropriate or eliminating the retention requirement altogether for documents that are not useful to the public.

27. As we proposed in the *NPRM*, for those documents we believe should be retained for the entire license term (including issues/programs lists and Children's Television Programming Reports), we will update our rules to reflect the current eight-year license term for both television and radio licenses. We will also require that those documents required to be retained for the full eight-year term be retained until the grant of the renewal application is final, *i.e.* no longer subject to reconsideration, review, or appeal either at the FCC or in the courts. This revision will ensure that those documents we believe should be available to the public for the entire license term remain available until final action has been taken on the license renewal application, thus facilitating monitoring of licensee performance by interested parties and their participation in the license renewal process. We disagree with those commenters who argued that the retention period for issues/programs lists, which is now 5 or 7 years based on the former license term for radio and TV stations, be reduced. The lists contain information about licensee compliance with public interest obligations which is relevant to the evaluation of licensee performance at renewal, and must continue to be available throughout the license term and until final grant of the next renewal application. Similarly, we decline to reduce the retention period for Children's Television Programming Reports, as one commenter suggested. Compliance with our children's programming requirements is an important issue to be examined at time of renewal. Consequently, these reports also must remain available through the entire license term and until final grant of the next renewal application.

28. In addition, as we proposed in the *NPRM*, we have decided to shorten the public file retention period for most applications filed with the FCC. Our current rules generally require that all applications be retained for the term of the license. The applications subject to this retention period include, for example, license assignment and transfer applications and applications for major facilities modifications. As we noted in the *NPRM*, and as many commenters agreed, these applications are most relevant to the public during the period they are pending before the FCC or the courts. Moreover, much of the information contained in these applications is available in other public file documents; information about the applicant's ownership structure, for example, is also available in the ownership reports. Accordingly, we will require that applications and related materials be retained in the public file only until final action has been taken on the application, except that new construction permit applications and applications for assignment or transfer of license that are granted pursuant to a waiver showing must be retained for as long as the waiver is in effect. With respect to these latter applications, the Commission has granted the waiver based, in part, on representations contained in the application and waiver exhibit. We believe these applications must remain available to the public for the entire period the waiver is in effect to ensure the public can assist the FCC in evaluating licensee performance in light of the representations made in the application and waiver request. Commenters that addressed this issue generally agreed that applications granted pursuant to a waiver request should be retained. Finally, we will also require that renewal applications granted on a short-term basis be retained throughout the short-term license period and until completion of the next renewal review. As the performance of these licensees has lead to imposition of a short-term renewal sanction, it is especially important that these renewal applications remain available to the public over the entire, shortened license term.

29. Regarding other possible means of streamlining our retention period requirements, we have concluded that we will require licensees to retain only the most recent, complete ownership report (FCC Form 323) in the public file, together with any subsequent statements filed with the FCC certifying that the current report is accurate. The current rule requires retention of all ownership reports for the term of the license. We agree with those commenters who argued that the most recent ownership report contains current information regarding the licensee's ownership structure, and that it is unnecessary to require licensees to retain previous ownership reports filed during the license term that contain out-of-date information. In the unusual case that a member of the public desires access to previous ownership information, these reports can be obtained from the

Commission. We note that the Commission has proposed, in a proceeding examining ways to streamline Mass Media applications, rules, and processes, to decrease the frequency with which Ownership Reports for commercial and noncommercial broadcast stations must be filed with the Commission. The changes to our public file requirements adopted herein will, of course, be subject to the outcome of that proceeding.

30. To further reduce the paperwork burden on licensees, as suggested by some licensees we will revise our current requirement that licensees retain in their public inspection files contracts required to be filed with the Commission under § 73.3613 of the rules. Rather than requiring copies of all such contracts to be kept in the public file, we will permit stations, as an alternative option, to maintain an up-to-date list identifying all such contracts and to provide copies to requesting parties within seven days. We believe this revision will reduce the burden on licensees, and especially on group owners who presently may have to retain multiple copies of the same agreement. At the same time, the public will have immediate access to a complete list of such contracts pertaining to the licensee, and can rapidly obtain any specific documents they wish to review.

31. Finally, with regard to communications (including e-mail) received from the public by commercial broadcasters regarding operation of their station and required to be maintained in the public file pursuant to current § 73.1202 of the rules, we will retain the current three year retention period for such communications. We will not extend the retention period for such letters to coincide with the eight year license term. We believe that an eight year retention requirement would be overly burdensome, and that older letters are less relevant to current licensee performance. While we will not extend the retention period for such communications beyond the existing three year term, we decline to shorten the retention period, or to eliminate the retention requirement altogether, as advocated by some commenters who argued that these letters are rarely requested by the public or used by the licensee or others in connection with a contested license renewal, especially in light of the expedited renewal procedures mandated by the 1996 Telecommunications Act. We are not persuaded by these arguments, and continue to believe that these letters and e-mails, retained for a three-year period, can play a helpful role in assisting the public in monitoring station performance. A member of the public may, for example, wish to know whether others have expressed similar concerns in letters to the station during the previous several years. We consequently believe a three-year retention period for letters and e-mails is warranted and will help promote a dialogue between stations and their communities.

32. In light of our goal to reduce unnecessary paperwork burdens, we will delete the requirement that letters from the public received by commercial TV licensees be separated into programming and non-programming subject categories. The burden imposed on licensees by this requirement seems to outweigh the relatively minimal benefit to those members of the public interested in reviewing these letters. Our rules will still require that licensees maintain a separate file containing letters requesting broadcast time for political candidates, making these letters more readily available. In addition, we note that licensees are required to prepare a summary at time of renewal of any letters they have received regarding violent programming, thereby assisting members of the public interested in letters received by licensees on this issue.

33. *Electronic Public File Option.* We will adopt our proposal to give stations the voluntary option of maintaining all or part of their public inspection file in a computer database rather than in paper files. We noted in the *NPRM* that many stations are equipped with computers and make information available to the public on their own World Wide Web home pages on the internet. Stations that post their ''electronic'' public files on the World Wide Web increase the number of locations from which these files may be accessed. Such measures can facilitate communication between licensees and their communities that can lead to better service to the public. Commenters generally supported giving stations the option to use computer technology to maintain and improve access to their public file, as long as such use is voluntary and not required. As proposed in the *NPRM*, a station that chooses the option of maintaining an ''electronic'' public file will be required to make a computer terminal available to members of the public interested in reviewing the station's file, and will be required to provide paper copies of such public file materials upon request.

34. *Contents of Local Public Inspection File.* To summarize the actions we are taking today to update, clarify, and revise our public inspection file rules, following is a list of our revised public file requirements. In addition to the revisions discussed above, this list includes certain other revisions and clarifications addressed in the *NPRM* and in comments as well as other modifications, more editorial in nature, designed to shorten and clarify the rules.

(i) *Authorization.* All licensees will be required to retain a copy of their current authorization, as well as any other documents necessary to reflect any modifications thereto or conditions that the Commission has placed on the authorization. Our current rule does not require that authorizations be maintained in the public file. This revision will ensure that the public has ready access to the technical parameters of the station license and any conditions on station operation imposed by the FCC.

(ii) *Applications and related materials.* We will require retention of applications filed with the FCC only until final action has been taken on the application, except that applications for a construction permit and applications for assignment or transfer of license granted, in either case, pursuant to a waiver must be retained for as long as the waiver remains in effect. In addition, renewal applications granted on a short-term basis must be retained through the short-term renewal review and until final grant of the next renewal application.

(iii) *Citizen Agreements.* As under the current rules, we will continue to require that a copy of every written citizen agreement be retained in the file for the term of the agreement.

(iv) *Contour maps.* As under the current rules, we will continue to require that applicants, permittees, and licensees retain in the file copies of any service contour maps submitted with any application tendered for filing with the FCC, together with any other information in the application showing service contours and/or main studio and transmitter location. These documents must be retained for as long as they reflect current, accurate information about the station.

(v) *Ownership Reports and related materials.* We will require licensees to retain only the most recent, complete ownership report (FCC Form 323) and any statement certifying the continuing accuracy of the report, until replaced by a new, complete report.

(vi) *List of contracts required to be filed with the FCC.* We will give licensees the option either of retaining in the public file a copy of all contracts

required to be filed with the FCC under § 73.3613, as our rules currently require, or of retaining an up-to-date list identifying all such contracts. Licensees who choose this latter option will be required to provide copies of such contracts to requesting parties within seven days.

(vii) *Political file.* We are making no substantive changes to our current political file requirements. We decline to reduce the current two-year retention period for records required to be maintained in the political file, as requested by at least one commenter. These records are necessary to permit political candidates and others to verify that licensees have complied with their obligations relating to use of their facilities by candidates for political office. We are not persuaded that the current retention period is overly burdensome to licensees, and believe this retention period provides interested parties necessary and adequate access to these important records.

(viii) *Annual employment reports and related material.* We will require retention of all annual employment reports until grant of the next renewal application becomes final. The current rule requires retention of these reports for five years for radio licensees and seven years for TV licensees, based on the former license terms for these facilities.

(ix) *''The Public and Broadcasting'' manual.* We will require licensees to maintain in the public file an updated version of this manual, to be prepared by the FCC staff.

(x) *Letters from the public.* As under the current rule, commercial licensees will be required to retain for a period of three years written comments and suggestions received from the public regarding operation of their station. The revised rule will clarify that the rule extends to e-mail communications as well as letters, and will relieve commercial TV licensees of their current obligation to separate letters into programming and non-programming subject categories. For reasons of clarity, the rules governing retention of letters from the public (currently in § 73.1202 of our rules) will be incorporated into our public file rule for commercial stations (§ 73.3526 of our rules).

(xi) *Material relating to FCC investigation or complaint.* As under the current rule, licensees will be required to retain material relating to a matter which is the subject of an FCC complaint or investigation until the licensee is notified by the FCC that the material may be discarded. The current rule will be revised, however, to delete the requirement that licensees retain materials related solely to private disputes, as the FCC does not involve itself in such disputes.

(xii) *Issues/programs list.* Sections 73.3526(a)(8)(i) and 73.3527(a)(7) require licensees to prepare a quarterly issues/programs list that must be retained in the public file for the term of the license (5 or 7 years under the current rule, based on the former license term). The new rule will require retention of such lists until grant of the next renewal application becomes final.

(xiii) *Records regarding children's programming commercial limits.* The revised rule requires retention of such records until grant of the next renewal application becomes final, which is the revised retention period for children's television programming reports. The current rule is unclear, requiring retention of ''records sufficient to permit substantiation of the station's certification, in its license renewal application, of compliance * * *'' with the commercial limits. The revised rule will also clarify that commercial records must be placed in the station's public file no later than the tenth day of the quarter following the quarter in which the programming aired.

(xiv) *Children's Television Programming Reports.* The revised rule will require retention of such reports until final grant of the next renewal application. The current rule has a five-year retention period, based on the former license term.

(xv) *Local public notice announcements.* As under our current rules, applicants for renewal of license must retain in the public file a copy of the local public notice of filing announcement required by § 73.3580 of the rules, which must be retained for the same period of time as the renewal application.

(xvi) *Radio time brokerage agreements.* The revised rule requires retention of such agreements in the public file until the contract expires. The current rule has not been updated to reflect the specification of this retention period in the 1992 radio ownership rule *Report and Order,* 57 FR 18089 (April 29, 1992).

(xvii) *Must-carry or retransmission consent election.* As under our current rules, statements of a commercial TV station's election with respect to either must-carry or retransmission consent must be retained for the duration of the three year election period to which the statement applies.

35. *Noncommercial Educational Stations.* Section 73.3527 of our rules governing public file requirements for noncommercial educational stations is very similar to the rule for commercial stations, and we have made the applicable revisions discussed above to both rules. In addition, we have made the following revisions to the rule relating to noncommercial educational stations.

36. *Letters from the public.* Currently, unlike commercial licensees, noncommercial educational stations are not required to retain letters from the public regarding operation of the station. In the *NPRM,* we noted that the 1996 Telecommunications Act requires licensees to summarize in their renewal applications letters received from the public and maintained by the licensee regarding violent programming. As noncommercial licensees are not presently required to retain letters from the public, public television commenters sought guidance regarding the obligations of noncommercial licensees to retain letters regarding violent programming. We have concluded that such licensees may retain letters from the public if they choose, but we will not require them to do so. The issue of violent programming has almost exclusively been raised in connection with programming aired by commercial television licensees. In light of our overall goal of streamlining public file obligations where appropriate, we do not believe it is necessary to require noncommercial television licensees to retain letters regarding violent programming or other programming issues. However, we will require that all noncommercial television licensees include in their renewal applications a summary of any letters they receive regarding violent programming. We believe that this requirement is appropriate in light of Congress' concern with the issue of violent programming, and will help ensure that the Commission and the public are kept informed of concerns raised by the public about such programming on both commercial and noncommercial stations.

37. *Ownership Reports.* We will revise § 73.3527 to require that noncommercial licensees retain a copy of their current complete ownership report (FCC Form 323-E) in the public file. Presently, that section of our rules does not reflect the language in Sections 73.3615(d)-(g) requiring that ownership reports be retained in the public inspection files of noncommercial licensees. Section 73.3615(d) requires that noncommercial licensee file ownership reports at renewal, as is required for commercial licensees. We will update our rules to mirror our new provision for commercial stations, discussed above.

38. *Donor's Lists.* One commenter advocated that we eliminate the

requirement that noncommercial broadcast licensees include in their public file a list of donors supporting specific programs. We disagree that this provision is obsolete. The donor list requirement is tied to our sponsorship identification requirements, the basic premise of which is that the public is entitled to know by whom they are being persuaded. The donor list requirement for noncommercial licensees is related to the Commission's determination that noncommercial educational stations are permitted to limit their on-air program sponsorship announcements to major donors or underwriters only, but must maintain a complete donor list in their public file. The donor lists therefore provide the only complete information regarding program sponsorship on noncommercial stations, and will be retained.

IV. Administrative Matters

39. *Paperwork Reduction Act of 1995 Analysis.* The action contained herein has been analyzed with respect to the Paperwork Reduction Act of 1995 and found to impose new or modified reporting and recordkeeping requirements or burdens on the public. Implementation of these new or modified reporting and recordkeeping requirements will be subject to approval by the Office of Management and Budget as prescribed by the Act.

V. Final Regulatory Flexibility Analysis

40. As required by the Regulatory Flexibility Act (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Review of the Commission's Rules Regarding the Main Studio and Public Inspection File of Broadcast Television and Radio Stations Notice of Proposed Rule Making in MM Docket No. 97–138 (''NPRM'')*, 12 FCC Rcd 6993, 7011 (1997). The Commission sought written public comment on the proposals in the *NPRM*, including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

Need for Objectives and Action

41. The main studio and public inspection file rules seek to ensure that members of the local community have access to the broadcast stations that are obligated under the FCC's rules to serve them. Our goals in this proceeding are to relieve undue regulatory burdens on licensees while retaining their basic obligations to serve their communities of license, and adopt a rule that is clear and easy to administer.

42. This *Report and Order* adopts rules that relax the main studio rule to reduce the burdens on licensees of broadcast stations, and provide them greater flexibility in locating their main studios. The *Report and Order* replaces the current requirement—that the main studio be located within a station's principal community contour—with a new standard that allows a station to locate its main studio within the principal community contour of any station (in any service) licensed to its community or within 25 miles of the center of its community of license, whichever it chooses. This standard fulfills the goals set in this proceeding. It is clear and easy to administer, and it strikes a balance between ensuring that the public has reasonable access to each station's main studio and public file and minimizing regulatory burdens on licensees. This rule should continue to ensure that the main studio is reasonably accessible to a station's community of license, and grant more flexibility to licensees of broadcast stations. We also believe that this amendment of the main studio rule will lessen the disproportionate effect that the previous rule had on owners of smaller stations.

43. The *Report and Order* also amends the local public inspection file rules to provide that licensees keep their public files at their main studio, wherever located, rather than in the community, as previously required. In addition, the *Report and Order* clarifies and updates aspects of the public inspection file rules regarding contents. These changes will reduce burdens on licensees providing access and the public seeking information. Licensees with out-of-community main studios will be able to exercise dominion over their public files, making sure the files are complete and available to the public seeking information, and that personnel are available to answer questions if necessary. This will also benefit the public.

Significant Issues Raised by Public Comments in Response to the IRFA

44. No comments were received specifically in response to the IRFA attached to the *NPRM*. Most commenters, agree generally that the Commission should amend the rule. Many commenters, agree generally with the combination approach for location of the main studio we adopt in the rule. Some of these commenters proposed amendments that would benefit only multiple station licensees, and others proposed amending the rule to allow licensees to locate their main studios at a more distant location (e.g., 40–50 miles from city-center, or within a ''market'' rather than community) than we adopt in our rule today. We considered the potential significant economic impact of these rules on small entities, and determined that our approach would benefit more small entities than those proposed by commenters and not adopted.

Description and Estimate of the Number of Small Entities To Which Rules Will Apply

Definition of a ''Small Business''

45. Under the RFA, small entities may include small organizations, small businesses, and small governmental jurisdictions. 5 U.S.C. 601(6). The RFA, 5 U.S.C. 601(3), generally defines the term ''small business'' as having the same meaning as the term ''small business concern'' under the Small Business Act, 15 U.S.C. 632. A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (''SBA''). Pursuant to 4 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency after consultation with the Office of Advocacy of the SBA and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

Issues in Applying the Definition of a ''Small Business''

46. As discussed below, we could not precisely apply the foregoing definition of ''small business'' in developing our estimates of the number of small entities to which the rules will apply. Our estimates reflect our best judgments based on the data available to us.

47. An element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific radio or television station is dominant in its field of operation. Accordingly, the following estimates of small businesses to which the new rules will apply do not exclude any radio or television station from the definition of a small business on this basis and are therefore overinclusive to that extent. An additional element of the definition of ''small business'' is that the entity must be independently owned and operated. As discussed further below, we could not fully apply this criterion, and our estimates of small businesses to which the rules may apply may be overinclusive to this extent. The SBA's general size standards are

developed taking into account these two statutory criteria. This does not preclude us from taking these factors into account in making our estimates of the numbers of small entities.

48. With respect to applying the revenue cap, the SBA has defined ''annual receipts'' specifically in 13 CFR 121.104, and its calculations include an averaging process. We do not currently require submission of financial data from licensees that we could use in applying the SBA's definition of a small business. Thus, for purposes of estimating the number of small entities to which the rules apply, we are limited to considering the revenue data that are publicly available, and the revenue data on which we rely may not correspond completely with the SBA definition of annual receipts.

49. Under SBA criteria for determining annual receipts, if a concern has acquired an affiliate or been acquired as an affiliate during the applicable averaging period for determining annual receipts, the annual receipts in determining size status include the receipts of both firms. 13 CFR 121.104(d)(1). The SBA defines affiliation in 13 CFR 121.103. In this context, the SBA's definition of affiliate is analogous to our attribution rules. Generally, under the SBA's definition, concerns are affiliates of each other when one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. 13 CFR 121.103(a)(1). The SBA considers factors such as ownership, management, previous relationships with or ties to another concern, and contractual relationships, in determining whether affiliation exists. 13 CFR 121.103(a)(2). Instead of making an independent determination of whether television stations were affiliated based on SBA's definitions, we relied on the databases available to us to provide us with that information.

Estimates Based on Census Data

50. The rules proposed in this *Notice of Proposed Rule Making* will apply to full service television and radio stations. The Small Business Administration defines a television broadcasting station that has no more than $10.5 million in annual receipts as a small business. Television broadcasting stations consist of establishments primarily engaged in broadcasting visual programs by television to the public, except cable and other pay television services. Included in this industry are commercial, religious, educational, and other television stations. Also included are establishments primarily engaged in television broadcasting and which produce taped television program materials. Separate establishments primarily engaged in producing taped television program materials are classified under another SIC number.

51. There were 1,509 television stations operating in the nation in 1992. That number has remained fairly constant as indicated by the approximately 1,580 operating television broadcasting stations in the nation as of June 1998. For 1992 the number of television stations that produced less than $10.0 million in revenue was 1,155 establishments. Thus, the proposed rules will affect approximately 1,569 television stations; approximately 77%, or 1,208 of those stations are considered small businesses. We use the 77 percent figure of TV stations operating at less than $10 million for 1992 and apply it to the 1998 total of 1569 TV stations to arrive at stations categorized as small businesses. These estimates may overstate the number of small entities since the revenue figures on which they are based do not include or aggregate revenues from non-television affiliated companies. We recognize that the proposed rules may also affect minority and women owned stations, some of which may be small entities. In 1995, minorities owned and controlled 37 (3.0%) of 1,221 commercial television stations in the United States. According to the U.S. Bureau of the Census, in 1987 women owned and controlled 27 (1.9%) of 1,342 commercial and non-commercial television stations in the United States.

52. The proposed rule changes would also affect radio stations. The SBA defines a radio broadcasting station that has no more than $5 million in annual receipts as a small business. A radio broadcasting station is an establishment primarily engaged in broadcasting aural programs by radio to the public. Included in this industry are commercial religious, educational, and other radio stations. Radio broadcasting stations which primarily are engaged in radio broadcasting and which produce ratio program materials are similarly included. However, radio stations which are separate establishments and are primarily engaged in producing radio program material are classified under another SIC number. The 1992 Census indicates that 96 percent (5,861 of 6,127) of radio station establishments produced less than $5 million in revenue in 1992. Official Commission records indicate that 11,334 individual radio stations were operating in 1992. As of June 1998, official Commission records indicate that 12,329 radio stations are currently operating.

Alternative Classification of Small Television Stations

53. An alternative way to classify small television stations is by the number of employees. The Commission currently applies a standard based on the number of employees in administering its Equal Employment Opportunity (''EEO'') rule for broadcasting. Thus, radio or television stations with fewer than five full-time employees are exempted from certain EEO reporting and recordkeeping requirements.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

54. The *Report and Order* adopts modifications to existing recordkeeping requirements. In general, these rules will allow broadcasters greater flexibility in locating their main studios, and would simply describe more specifically where a licensee must retain the public file it is already required by the Commission's rules to maintain. Generally, the costs of compliance will be reduced for all entities. The *Report and Order* also addresses how a licensee can make its public inspection file available via the internet, but broadcasters would retain the discretion not to utilize internet technology at all. The *Report and Order* clarifies which materials are required to be kept in the public file, and clarifies the required retention period for public file materials. No special skills will be necessary to comply with these requirements.

55. Specifically, the *Report and Order* requires stations to make available, by mail upon telephone request, photocopies of documents in the public file. The station may require the person requesting the copies to pay the reasonable cost of photocopying prior to mailing, and the station will pay postage. The *Report and Order* requires stations to provide callers, if they wish to receive one, a copy of the new edition of ''The Public and Broadcasting'' free of charge. The *Report and Order* requires licensees to assist callers in this process and answer questions they may have about the actual contents of the station's public file, such as the number of pages and time periods covered by a particular report or the types and dates of applications maintained in the station's public file. Any increased burdens associated with these accommodations will apply equally to all stations.

56. With respect to the contents of the local public inspection file, several

changes affect reporting, recordkeeping and compliance. These changes are: all licensees must retain a copy of their current authorization, as well as any other documents necessary to reflect any modifications thereto or conditions that the Commission has placed on the authorization. This does not increase any burdens, merely requires the licensee to keep its authorization in its public file as well as in the station.

57. Applications filed with the FCC must be retained only until final action has been taken on the application, except that applications for a construction permit and applications for assignment or transfer of license granted pursuant to a waiver must be retained for as long as the waiver remains in effect. Renewal applications granted on a short-term basis must be retained through the short-term renewal review and until final grant of the next renewal application. This reduces the burden on licensees, both by clearly defining what must be retained, and the period during which it must be retained.

58. Licensees must retain only the most recent, complete ownership report (FCC Form 323) and any statement certifying the continuing accuracy of the report, until replaced by a new, complete report. This clarification reduces burdens on all licensees.

59. Licensees may either retain in the public file a copy of all contracts referenced under § 73.3613 of the Commission's Rules, or retain an up-to-date list identifying all such contracts, and then provide copies of such contracts to requesting parties within seven days. The list option reduces paperwork burdens on licensees.

60. Licensees must maintain in the public file an updated version of ''The Public and Broadcasting'' manual.

61. Letters from the public required to be retained are clarified to include e-mail communications. To mitigate any burden of increased paperwork resulting from retention of computer e-mails, licensees may, at their option maintain such documents on diskette rather than in hard copy. Commercial TV licensees need not separate letters into programming and non-programming subject categories, reducing burdens required in maintaining two separate categories.

62. With respect to material relating to FCC investigation or complaint, licensees are no longer required to retain materials related solely to private disputes, as the FCC does not involve itself in such disputes.

63. Radio time brokerage agreements must be retained in the public file until the contract expires. This is a clarification.

64. Retention periods for the following are updated to reflect the current eight-year license term, noting that all items are to be retained until grant of the next renewal becomes final: Issues/programs list; records regarding children's programming commercial limits; Children's Television programming reports; Local public notice announcements. Most changes herein are no more burdensome than the previous rule.

65. With respect to rules specific to noncommercial educational stations, we have amended the public inspection file requirements to require noncommercial licensees to retain a copy of their current complete ownership report (FCC Form 323–E) in the public file. All noncommercial television licensees must also include in their renewal applications a summary of any letters they receive regarding violent programming. These changes are not burdensome to small businesses.

Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

66. We considered four options to achieve our goals in this proceeding. Our first goal was to balance reasonable access to the public and regulatory burdens on licensees, and our second goal was to achieve clarity in our rules and ease of administration. The approach we have chosen will grant flexibility to licensees of multiple stations, as well as licensees of smaller stations, and those that are the sole local services in a community. One of our concerns in adopting a rule was to address the differential treatment larger and smaller stations received under the previous rule. We believe that the rule we adopt today addresses this differential treatment and assures that the main studio remains in the primary reception area of a station licensed to the same community. It also grants small station licensees a much wider degree of latitude in choosing main studio locations compared to the latitude they had under the previous rule.

67. As stated above, we have adopted an accommodation which applies to all licensees. We considered and rejected other accommodations mentioned in the *NPRM* and proposed by commenters. We considered all of the alternate suggestions and have determined that the accommodation we require in this rule fulfills our stated goals of balancing public access with regulatory burden and ease and clarity of administration. We believe that requiring stations to provide transportation to requesters, to transport the public file to them or open the main studio during non-business hours would be unnecessarily burdensome to station owners, large and small.

68. We have considered whether only commercial licensees should continue to be required to retain letters from the public. Since the 1996 Telecommunications Act requires licensees to summarize in their renewal applications letters received from the public and maintained by the licensee regarding violent programming, commenters asked to address whether noncommercial licensees would be required to retain these letters. In the interest of streamlining and reducing burdens, we have not required noncommercial television licensees to retain letters from the public regarding violent programming or other programming issues. As stated above, noncommercial television licensees will submit a summary of such letters with their renewal applications.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

None.

69. The Commission will send a copy of the *Main Studio and Public Inspection File Report and Order,* including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, see 5 U.S.C. § 801(a)(1)(A). In addition, the Commission will send a copy of the *Main Studio and Public Inspection File Report and Order,* including FRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

70. Accordingly, it is ordered that, pursuant to the authority contained in Sections 154, 303, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154, 303, and 307, Sections 73.1125, 73.1202, 73.3526 and 73.3527 of the Commission's Rules, 47 CFR §§ 73.1125, 73.1202, 73.3526 and 73.3527 are amended.

71. It is further ordered that the Commission staff shall dismiss all main studio and/or public file waiver requests currently pending unless parties submitting such waiver requests amend their requests by October 16, 1998 to show why the relief they request continues to be warranted given the newly revised main studio and public file rules.

72. These rules contain information collection requirements that are not effective until approved by the Office of Management and Budget. FCC will publish a document in the **Federal Register** announcing the effective date for these sections.

73. It is further ordered that the Commission's Office of Public Affairs, Reference Operations Division, shall send a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

71. It is further ordered that this proceeding is terminated.

List of Subjects in 47 CFR Part 73

Radio, Television.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

Rule Changes

Part 73 of Title 47 of the U.S. Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

2. Section 73.1125 is revised to read as follows:

§ 73.1125 Station main studio location.

(a) Except for those stations described in paragraph (b) of this section, each AM, FM, and TV broadcast station shall maintain a main studio at one of the following locations:

(1) within the station's community of license;

(2) at any location within the principal community contour of any AM, FM, or TV broadcast station licensed to the station's community of license; or

(3) within twenty-five miles from the reference coordinates of the center of its community of license as described in § 73.208(a)(1).

Note to paragraph (a): The principal community contour of AM stations that simulcast on a frequency in the 535–1605 kHz band and on a frequency in the 1605–1705 kHz band shall be the 5 mV/m contour of the lower band operation during the term of the simultaneous operating authority. Upon termination of the 535–1605 kHz band portion of the dual frequency operation, the principal community contour shall become the 5 mV/m of the remaining operation in the 1605–1705 kHz band.

(b) The following stations are not required to maintain their main studio at the locations described in paragraph (a) of this section.

(1) AM stations licensed as synchronous amplifier transmitters (''AM boosters'') or,

(2) AM, FM, or TV stations, when good cause exists for locating the main studio at a location other than that described in paragraph (a) of this section, and when so doing would be consistent with the operation of the station in the public interest.

(c) Relocation of the main studio may be made:

(1) From one point to another within the locations described in paragraph (a) this section or from a point outside the locations specified in paragraph (a) to one within those locations, without specific FCC authority, but notification to the FCC in Washington shall be made promptly.

(2) Written authority to locate a main studio outside the locations specified in paragraph (a) of this section for the first time must be obtained from the Audio Services Division, Mass Media Bureau for AM and FM stations, or the Television Branch, Video Services Division, Mass Media Bureau for television stations before the studio may be moved to that location. Where the main studio is already authorized at a location outside those specified in paragraph (a), and the licensee or permittee desires to specify a new location also located outside those locations, written authority must also be received from the Commission prior to the relocation of the main studio. Authority for these changes may be requested by filing a letter with an explanation of the proposed changes with the appropriate division. Licensees or permittees should be aware that the filing of such a letter request does not imply approval of the relocation request, because each request is addressed on a case-by-case basis. A filing fee is required for commercial AM, FM, or TV licensees or permittees filing a letter request under this section (*see* § 1.1104).

(d) Each AM, FM, and TV broadcast station shall maintain a local telephone number in its community of license or a toll-free number.

3. Section 73.3526 is revised to read as follows:

§ 73.3526 Local public inspection file of commercial stations.

(a) *Responsibility to maintain a file.* The following shall maintain for public inspection a file containing the material set forth in this section.

(1) Applicants for a construction permit for a new station in the commercial broadcast services shall maintain a public inspection file containing the material, relating to that station, described in paragraphs (e)(2) and (e)(10) of this section. A separate file shall be maintained for each station for which an application is pending. If the application is granted, paragraph (a)(2) of this section shall apply.

(2) Every permittee or licensee of an AM, FM, or TV station in the commercial broadcast services shall maintain a public inspection file containing the material, relating to that station, described in paragraphs (e)(1) through (e)(10) and paragraph (e)(13) of this section. In addition, every permittee or licensee of a commercial TV station shall maintain for public inspection a file containing material, relating to that station, described in paragraphs (e)(11) and (e)(15) of this section, and every permittee or licensee of a commercial AM or FM station shall maintain for public inspection a file containing the material, relating to that station, described in paragraphs (e)(12) and (e)(14) of this section. A separate file shall be maintained for each station for which an authorization is outstanding, and the file shall be maintained so long as an authorization to operate the station is outstanding.

(b) *Location of the file.* The public inspection file shall be maintained at the main studio of the station. An applicant for a new station or change of community shall maintain its file at an accessible place in the proposed community of license or at its proposed main studio.

(c) *Access to material in the file.* (1) The file shall be available for public inspection at any time during regular business hours. All or part of the file may be maintained in a computer database, as long as a computer terminal is made available, at the location of the file, to members of the public who wish to review the file. Material in the public inspection file shall be made available for printing or machine reproduction upon request made in person. The applicant, permittee, or licensee may specify the location for printing or reproduction, require the requesting party to pay the reasonable cost thereof, and may require guarantee of payment in advance (e.g., by requiring a deposit, obtaining credit card information, or any other reasonable method). Requests for copies shall be fulfilled within a reasonable period of time, which generally should not exceed 7 days.

(2) The applicant, permittee, or licensee shall make available, by mail upon telephone request, photocopies of documents in the file, and the station shall pay postage. Licensees shall mail the most recent version of ''The Public and Broadcasting'' to any member of the public that requests a copy. Licensees shall be prepared to assist members of the public in identifying the documents they may ask to be sent to them by mail, for example, by describing to the caller,

if asked, the period covered by a particular report and the number of pages included in the report.

(d) *Responsibility in case of assignment or transfer.* (1) In cases involving applications for consent to assignment of broadcast station construction permits or licenses, with respect to which public notice is required to be given under the provisions of § 73.3580 or § 73.3594, the file mentioned in paragraph (a) of this section shall be maintained by the assignor. If the assignment is consented to by the FCC and consummated, the assignee shall maintain the file commencing with the date on which notice of the consummation of the assignment is filed with the FCC. The assignee shall retain public file documents obtained from the assignor for the period required under these rules.

(2) In cases involving applications for consent to transfer of control of a permittee or licensee of a broadcast station, the file mentioned in paragraph (a) of this section shall be maintained by the permittee or licensee.

(e) *Contents of the file.* The material to be retained in the public inspection file is as follows:

(1) *Authorization.* A copy of the current FCC authorization to construct or operate the station, as well as any other documents necessary to reflect any modifications thereto or any conditions that the FCC has placed on the authorization. These materials shall be retained until replaced by a new authorization, at which time a copy of the new authorization and any related materials shall be placed in the file.

(2) *Applications and related materials.* A copy of any application tendered for filing with the FCC, together with all related material, and copies of Initial Decisions and Final Decisions in hearing cases pertaining thereto. If petitions to deny are filed against the application and have been served on the applicant, a statement that such a petition has been filed shall be maintained in the file together with the name and address of the party filing the petition. Applications shall be retained in the public inspection file until final action has been taken on the application, except that applications for a new construction permit granted pursuant to a waiver showing and applications for assignment or transfer of license granted pursuant to a waiver showing shall be retained for as long as the waiver is in effect. In addition, license renewal applications granted on a short-term basis shall be retained until final action has been taken on the license renewal application filed immediately following the shortened license term.

(3) *Citizen agreements.* A copy of every written citizen agreement. These agreements shall be retained for the term of the agreement, including any renewal or extension thereof.

Note to paragraph (e)(3): For purposes of this section, a citizen agreement is a written agreement between a broadcast applicant, permittee, or licensee, and one or more citizens or citizen groups, entered for primarily noncommercial purposes. This definition includes those agreements that deal with goals or proposed practices directly or indirectly affecting station operations in the public interest, in areas such as—but not limited to—programming and employment. It excludes common commercial agreements such as advertising contracts; union, employment, and personal services contracts; network affiliation, syndication, program supply contracts, etc. However, the mere inclusion of commercial terms in a primarily noncommercial agreement—such as a provision for payment of fees for future services of the citizen-parties (see ''Report and Order,'' Docket 19518, 57 FCC 2d 494 (1976))—would not cause the agreement to be considered commercial for purposes of this section.

(4) *Contour maps.* A copy of any service contour maps, submitted with any application tendered for filing with the FCC, together with any other information in the application showing service contours and/or main studio and transmitter location (State, county, city, street address, or other identifying information). These documents shall be retained for as long as they reflect current, accurate information regarding the station.

(5) *Ownership reports and related materials.* A copy of the most recent, complete ownership report filed with the FCC for the station, together with any statements filed with the FCC certifying that the current report is accurate, and together with all related material. These materials shall be retained until a new, complete ownership report is filed with the FCC, at which time a copy of the new report and any related materials shall be placed in the file. The permittee or licensee must retain in the public file either a copy of the contracts listed in such reports in accordance with § 73.3615(a)(4)(i), or an up-to-date list of such contracts. Licensees or permittees who choose to retain a list of contracts must provide a copy of any contracts to requesting parties within 7 days.

(6) *Political file.* Such records as are required by § 73.1943 to be kept concerning broadcasts by candidates for public office. These records shall be retained for the period specified in § 73.1943 (2 years).

(7) *Annual employment reports.* A copy of every annual employment report filed by the licensee or permittee for the station, together with all related material (Form 395–B). These materials shall be retained until final action has been taken on the station's next license renewal application.

(8) *The public and broadcasting.* At all times, a copy of the most recent version of the manual entitled ''The Public and Broadcasting.''

(9) *Letters and e-mail from public.* All written comments and suggestions received from the public regarding operation of the station, unless the letter writer has requested that the letter not be made public or when the licensee feels that it should be excluded from public inspection because of the nature of its content, such as a defamatory or obscene letter. Letters and electronic mail messages shall be retained for a period of three years from the date on which they are received by the licensee. For purposes of this section, written comments and suggestions received from the public include electronic mail messages transmitted via the internet. Licensees may retain e-mails either on paper or in a computer file. Licensees who choose to maintain a computer file of e-mails may make the file available to the public either by providing the public with access to a computer terminal at the location of the public file, or providing the public with a copy of such e-mails on computer diskette, upon request. In the case of identical communications, licensees and permittees may retain one sample copy of the letter or electronic mail message together with a list identifying other parties who sent identical communications.

(10) *Material relating to FCC investigation or complaint.* Material having a substantial bearing on a matter which is the subject of an FCC investigation or complaint to the FCC of which the applicant, permittee, or licensee has been advised. This material shall be retained until the applicant, permittee, or licensee is notified in writing that the material may be discarded.

(11)(i) *TV issues/programs lists.* For commercial TV broadcast stations, every three months a list of programs that have provided the station's most significant treatment of community issues during the preceding three month period. The list for each calendar quarter is to be filed by the tenth day of the succeeding calendar quarter (*e.g.*, January 10 for the quarter October—December, April 10 for the quarter January—March, etc.). The list shall include a brief narrative describing what

issues were given significant treatment and the programming that provided this treatment. The description of the programs shall include, but shall not be limited to, the time, date, duration, and title of each program in which the issue was treated. The lists described in this paragraph shall be retained in the public inspection file until final action has been taken on the station's next license renewal application.

(ii) *Records concerning commercial limits.* For commercial TV broadcast stations, records sufficient to permit substantiation of the station's certification, in its license renewal application, of compliance with the commercial limits on children's programming established in 47 U.S.C. 303a and 47 CFR 73.670. The records for each calendar quarter must be filed in the public inspection file by the tenth day of the succeeding calendar quarter (*e.g.*, January 10 for the quarter October—December, April 10 for the quarter January—March, etc.). These records shall be retained until final action has been taken on the station's next license renewal application.

(iii) *Children's television programming reports.* For commercial TV broadcast stations, on a quarterly basis, a completed Children's Television Programming Report (''Report''), on FCC Form 398, reflecting efforts made by the licensee during the preceding quarter, and efforts planned for the next quarter, to serve the educational and informational needs of children. The Report for each quarter is to be filed by the tenth day of the succeeding calendar quarter. The Report shall identify the licensee's educational and informational programming efforts, including programs aired by the station that are specifically designed to serve the educational and informational needs of children, and it shall explain how programs identified as Core Programming meet the definition set forth in § 73.671(c). The Report shall include the name of the individual at the station responsible for collecting comments on the station's compliance with the Children's Television Act, and it shall be separated from other materials in the public inspection file. These Reports shall be retained in the public inspection file until final action has been taken on the station's next license renewal application. Licensees shall publicize in an appropriate manner the existence and location of these Reports. For an experimental period of three years, licensees shall file these Reports with the Commission on an annual basis, *i.e.* four quarterly reports filed jointly each year, preferably in electronic form. These Reports shall be filed with the Commission on January 10, 1998, January 10, 1999, and January 10, 2000.

(12) *Radio issues/programs lists.* For commercial AM and FM broadcast stations, every three months a list of programs that have provided the station's most significant treatment of community issues during the preceding three month period. The list for each calendar quarter is to be filed by the tenth day of the succeeding calendar quarter (*e.g.*, January 10 for the quarter October—December, April 10 for the quarter January—March, etc.). The list shall include a brief narrative describing what issues were given significant treatment and the programming that provided this treatment. The description of the programs shall include, but shall not be limited to, the time, date, duration, and title of each program in which the issue was treated. The lists described in this paragraph shall be retained in the public inspection file until final action has been taken on the station's next license renewal application.

(13) *Local public notice announcements.* Each applicant for renewal of license shall, within 7 days of the last day of broadcast of the local public notice of filing announcements required pursuant to § 73.3580(h), place in the station's local public inspection file a statement certifying compliance with this requirement. The dates and times that the pre-filing and post-filing notices were broadcast and the text thereof shall be made part of the certifying statement. The certifying statement shall be retained in the public file for the period specified in § 73.3580 (for as long as the application to which it refers).

(14) *Radio time brokerage agreements.* For commercial radio stations, a copy of every agreement or contract involving time brokerage of the licensee's station or of another station by the licensee, with confidential or proprietary information redacted where appropriate. These records shall be retained as long as the contract or agreement is in force.

(15) *Must-carry or retransmission consent election.* Statements of a commercial television station's election with respect to either must-carry or retransmission consent as defined in § 76.64 of this chapter. These records shall be retained for the duration of the three year election period to which the statement applies.

Note 1 to paragraph (e): For purposes of this section, action taken on an application tendered with the FCC becomes final when that action is no longer subject to reconsideration, review, or appeal either at the FCC or in the courts.

Note 2 to paragraph (e): For purposes of this section, the term ''all related material'' includes all exhibits, letters, and other documents tendered for filing with the FCC as part of an application, report, or other document, all amendments to the application, report, or other document, copies of all documents incorporated therein by reference and not already maintained in the public inspection file, and all correspondence between the FCC and the applicant pertaining to the application, report, or other document, which according to the provisions of §§ 0.451 through 0.461 of this part are open for public inspection at the offices of the FCC.

4. Section 73.3527 is revised to read as follows:

§ 73.3527 Local public inspection file of noncommercial educational stations.

(a) *Responsibility to maintain a file.* The following shall maintain for public inspection a file containing the material set forth in this section.

(1) Applicants for a construction permit for a new station in the noncommercial educational broadcast services shall maintain a public inspection file containing the material, relating to that station, described in paragraph (e)(2) and (e)(11) of this section. A separate file shall be maintained for each station for which an application is pending. If the application is granted, paragraph (a)(2) of this section shall apply.

(2) Every permittee or licensee of an AM, FM, or TV station in the noncommercial educational broadcast services shall maintain a public inspection file containing the material, relating to that station, described in paragraphs (e)(1) through (e)(11) of this section. In addition, every permittee or licensee of a noncommercial educational TV station shall maintain for public inspection a file containing material, relating to that station, described in paragraphs (e)(12) of this section. A separate file shall be maintained for each station for which an authorization is outstanding, and the file shall be maintained so long as an authorization to operate the station is outstanding.

(b) *Location of the file.* The public inspection file shall be maintained at the main studio of the station. An applicant for a new station or change of community shall maintain its file at an accessible place in the proposed community of license or at its proposed main studio.

(c) *Access to material in the file.* (1) The file shall be available for public inspection at any time during regular business hours. All or part of the file may be maintained in a computer database, as long as a computer terminal

is made available, at the location of the file, to members of the public who wish to review the file. Material in the public inspection file shall be made available for printing or machine reproduction upon request made in person. The applicant, permittee, or licensee may specify the location for printing or reproduction, require the requesting party to pay the reasonable cost thereof, and may require guarantee of payment in advance (*e.g.*, by requiring a deposit, obtaining credit card information, or any other reasonable method). Requests for copies shall be fulfilled within a reasonable period of time, which generally should not exceed 7 days.

(2) The applicant, permittee, or licensee shall make available, by mail upon telephone request, photocopies of documents in the file, and the station shall pay postage. Licensees shall mail the most recent version of ''The Public and Broadcasting'' to any member of the public that requests a copy. Licensees shall be prepared to assist members of the public in identifying the documents they may ask to be sent to them by mail, for example, by describing to the caller, if asked, the period covered by a particular report and the number of pages included in the report.

(d) *Responsibility in case of assignment or transfer.* (1) In cases involving applications for consent to assignment of broadcast station construction permits or licenses, with respect to which public notice is required to be given under the provisions of § 73.3580 or § 73.3594, the file mentioned in paragraph (a) of this section shall be maintained by the assignor. If the assignment is consented to by the FCC and consummated, the assignee shall maintain the file commencing with the date on which notice of the consummation of the assignment is filed with the FCC. The assignee shall retain public file documents obtained from the assignor for the period required under these rules.

(2) In cases involving applications for consent to transfer of control of a permittee or licensee of a broadcast station, the file mentioned in paragraph (a) of this section shall be maintained by the permittee or licensee.

(e) *Contents of the file.* The material to be retained in the public inspection file is as follows:

(1) *Authorization.* A copy of the current FCC authorization to construct or operate the station, as well as any other documents necessary to reflect any modifications thereto or any conditions that the FCC has placed on the authorization. These materials shall be retained until replaced by a new authorization, at which time a copy of the new authorization and any related materials shall be placed in the file.

(2) *Applications and related materials.* A copy of any application tendered for filing with the FCC, together with all related material, and copies of Initial Decisions and Final Decisions in hearing cases pertaining thereto. If petitions to deny are filed against the application and have been served on the applicant, a statement that such a petition has been filed shall be maintained in the file together with the name and address of the party filing the petition. Applications shall be retained in the public inspection file until final action has been taken on the application, except that applications for a new construction permit granted pursuant to a waiver showing and applications for assignment or transfer of license granted pursuant to a waiver showing shall be retained for as long as the waiver is in effect. In addition, license renewal applications granted on a short-term basis shall be retained until final action has been taken on the license renewal application filed immediately following the shortened license term.

(3) *Contour maps.* A copy of any service contour maps, submitted with any application tendered for filing with the FCC, together with any other information in the application showing service contours and/or main studio and transmitter location (State, county, city, street address, or other identifying information). These documents shall be retained for as long as they reflect current, accurate information regarding the station.

(4) *Ownership reports and related materials.* A copy of the most recent, complete ownership report filed with the FCC for the station, together with any subsequent supplemental report or statement filed with the FCC certifying that the current report is accurate, and together with all related material. These materials shall be retained until a new, complete ownership report is filed with the FCC, at which time a copy of the new report and any related materials shall be placed in the file. The permittee or licensee must retain in the public file either a copy of the contracts listed in such reports in accordance with § 73.3615(d)(3), or an up-to-date list of such contracts. Licensees and permittees who choose to maintain a list of contracts must provide a copy of any contracts to requesting parties within 7 days.

(5) *Political file.* Such records as are required by § 73.1943 to be kept concerning broadcasts by candidates for public office. These records shall be retained for the period specified in § 73.1943 (2 years).

(6) *Annual employment reports.* A copy of every annual employment report (Form 395) filed by the licensee or permittee for the station, together with all related material. These materials shall be retained until final action has been taken on the station's next license renewal application.

(7) *The Public and Broadcasting.* At all times, a copy of the most recent version of the manual entitled ''The Public and Broadcasting.''

(8) *Issues/programs lists.* For nonexempt noncommercial educational broadcast stations, every three months a list of programs that have provided the station's most significant treatment of community issues during the preceding three month period. The list for each calendar quarter is to be filed by the tenth day of the succeeding calendar quarter (*e.g.*, January 10 for the quarter October–December, April 10 for the quarter January–March, etc.). The list shall include a brief narrative describing what issues were given significant treatment and the programming that provided this treatment. The description of the programs shall include, but shall not be limited to, the time, date, duration, and title of each program in which the issue was treated. The lists described in this paragraph shall be retained in the public inspection file until final action has been taken on the station's next license renewal application.

(9) *Donor lists.* The lists of donors supporting specific programs. These lists shall be retained for two years.

(10) *Local public notice announcements.* Each applicant for renewal of license shall, within 7 days of the last day of broadcast of the local public notice of filing announcements required pursuant to § 73.3580(h), place in the station's local public inspection file a statement certifying compliance with this requirement. The dates and times that the pre-filing and post-filing notices were broadcast and the text thereof shall be made part of the certifying statement. The certifying statement shall be retained in the public file for the period specified in § 73.3580 (for as long as the application to which it refers).

(11) *Material relating to FCC investigation or complaint.* Material having a substantial bearing on a matter which is the subject of an FCC investigation or complaint to the FCC of which the applicant, permittee, or licensee has been advised. This material shall be retained until the applicant, permittee, or licensee is notified in

writing that the material may be discarded.

(12) *Must-carry requests.* Noncommercial television stations requesting mandatory carriage on any cable system pursuant to § 76.56 of this chapter shall place a copy of such request in its public file and shall retain both the request and relevant correspondence for the duration of any period to which the request applies.

Note (1) to paragraph (e): For purposes of this section, a decision made with respect to an application tendered with the FCC becomes final when that decision is no longer subject to reconsideration, review, or appeal either at the FCC or in the courts.

Note (2) to paragraph (e): For purposes of this section, the term ''all related material'' includes all exhibits, letters, and other documents tendered for filing with the FCC as part of an application, report, or other document, all amendments to the application, report, or other document, copies of all documents incorporated therein by reference and not already maintained in the public inspection file, and all correspondence between the FCC and the applicant pertaining to the application, report, or other document, which according to the provisions of §§ 0.451 through 0.461 of the rules are open for public inspection at the offices of the FCC.

§ 73.1202 [Removed]

5. Section 73.1202 is removed.

[FR Doc. 98–24004 Filed 9–15–98; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 082798A]

Fisheries of the Exclusive Economic Zone Off Alaska; Community Development Quota Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Partial approval of the Community Development Plans for Multispecies Groundfish and Prohibited Species for the years 1998 through 2000.

SUMMARY: NMFS announces the partial approval of recommendations made by the State of Alaska (State) for the 1998 through 2000 multispecies groundfish and prohibited species Community Development Plans (CDPs) under the Western Alaska Community Development Quota (CDQ) Program. This action announces the decision by NMFS to approve the State's recommended CDPs, including the percentage allocations of the multispecies groundfish CDQ reserves and prohibited species quota (PSQ) reserves to each CDP, with the exception of certain vessels listed in the CDPs that NMFS determined are ineligible for approval at this time. This action also announces the availability of findings underlying NMFS's decision. This action is intended to further the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act.

DATES: Partial approval of the CDPs is effective October 16, 1998.

ADDRESSES: Copies of the findings made by NMFS in partially approving the State's recommendations may be obtained from the Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Gravel.

FOR FURTHER INFORMATION CONTACT: Sally Bibb, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

The Multispecies CDQ Program was developed by the North Pacific Fishery Management Council (Council) as Amendment 41 to the Fisheries Management Plan for the Bering Sea/Aleutian Islands Groundfish. Amendment 41 was approved by NMFS on September 12, 1997, and implemented under regulations at subpart C of 50 CFR part 679. Regulations establishing the groundfish CDQ reserves and PSQ reserves were published in the **Federal Register** on February 19, 1998 (63 FR 8356), and a final rule implementing the administrative and catch monitoring requirements for the multispecies (MS) CDQ Program was published in the **Federal Register** on June 4, 1998 (63 FR 30381).

Eligible western Alaska communities submitted six proposed CDPs to the State under § 679.30. The CDPs include requests for allocations of the available multispecies groundfish CDQ reserves and PSQ reserves established at § 679.31. The State conducted a public hearing on September 9, 1997, in Anchorage, Alaska, during which all interested persons had an opportunity to be heard. The hearing covered the substance and content of the proposed CDPs in such a manner that the general public, and particularly the affected parties, had a reasonable opportunity to understand the impact of each proposed CDP. The State made available for public review all State of Alaska materials pertinent to the hearing at the time the hearing was announced. The public hearing held by the State satisfied the requirements of § 679.30(b).

The State consulted the Council concerning the proposed CDPs during the Council's September 1997 and April 1998 meetings. The Council reviewed copies of the CDP executive summaries, summary sheets, and the State's recommended allocations and concurred in the State's recommendations.

The State sent its recommendations for approval of the proposed CDPs to NMFS on July 6, 1998. The State's allocation recommendations are effective for 1998 through 2000 for all species groups allocated to the groundfish CDQ reserves and PSQ reserves, except arrowtooth flounder, squid, ''other species'', chinook salmon, and non-chinook salmon. Allocation recommendations for these five species groups are effective for 1998 only. Delaying the 1999 and 2000 allocation recommendations for these five species groups will allow the State to provide for bycatch needs for (1) the fixed gear sablefish CDQ fishery when it is integrated into the multispecies groundfish CDQ fisheries in 1999, and (2) the pollock CDQ fishery if Amendment 45 and its implementing regulations are approved by NMFS.

New regulations governing the MS CDQ fisheries promulgated by NMFS on June 4, 1998, require that a fishing plan for each vessel and processor proposed as eligible to participate in the MS groundfish CDQ be submitted in the CDP. NMFS has reviewed fishing plans for 39 catcher vessels, 24 catcher/processors, and five shoreside processing plants and determined that 38 catcher vessels, 13 catcher/processors, and five shoreside processing plants can be approved at this time as eligible for the MS CDQ fisheries. The remaining catcher vessel and 11 catcher/processors do not meet the requirements for eligibility because incomplete or incorrect information was provided in the proposed CDP. NMFS has notified the CDQ groups of the deficiencies in the fishing plans for these vessels and the specific information that must be provided before these vessels will be approved. Vessels not approved as eligible vessels with the CDP may be added later through an amendment to the CDP.

With the exception of the vessels mentioned above, NMFS has determined that the State's recommendations for approval of proposed CDPs are consistent with the community eligibility conditions and evaluation criteria and other applicable provisions of the Federal regulations

governing the CDQ Program. The allocations to each CDQ group are presented in the table below. NMFS's findings regarding this decision also are available (see **ADDRESSES**). CDQ fishing for multispecies groundfish is authorized under § 679.23 at 1200 hours, Alaska local time, October 1, 1998.

STATE OF ALASKA MULTISPECIES GROUNDFISH AND PROHIBITED SPECIES COMMUNITY DEVELOPMENT QUOTA ALLOCATIONS

Species or species group	APICDA percent	BBEDC percent	CBSFA percent	CVRF percent	NSEDC percent	YDFDA percent
Allocations for 1998–2000						
Groundfish:						
BS Sablefish	16	20	10	17	18	19
AI Sablefish	16	20	10	17	18	19
Pacific Cod	16	20	10	17	18	19
WAI Atka Mackerel	20	17	10	17	16	20
CAI Atka Mackerel	20	17	10	17	16	20
EAI/BS Atka Mackerel	20	17	10	17	16	20
Yellowfin Sole	29	25	8	5	5	28
Rock Sole	10	20	10	20	20	20
BS Greenland Turbot	16	25	14	1	20	24
AI Greenland Turbot	18	18	5	14	26	19
Flathead Sole	20	20	10	15	15	20
Other Flatfish	20	20	10	15	15	20
BS Pacific Ocean Perch	20	17	10	17	16	20
WAI Pacific Ocean Perch	20	17	10	17	16	20
CAI Pacific Ocean Perch	20	17	10	17	16	20
EAI Pacific Ocean Perch	20	17	10	17	16	20
BS Other Red Rockfish	20	17	10	17	16	20
AI Sharpchin/Northern	20	17	10	17	16	20
AI Shortraker/Rougheye	17	20	9	17	18	19
BS Other Rockfish	16	20	8	18	19	19
BS Other Rockfish	16	20	8	18	19	19
Prohibited Species:						
Zone 1 Red King Crab	19	21	9	15	15	21
Zone 1 Bairdi Tanner Crab	24	25	7	9	9	26
Zone 2 Bairdi Tanner Crab	24	25	7	9	9	26
Opilio Tanner Crab	26	23	9	8	8	26
Pacific Halibut	20	22	8	13	14	23
Allocations for 1998 only						
Arrowtooth Flounder	19	21	9	15	15	21
Squid	19	18	10	17	16	20
Other Species	19	22	9	14	14	22
Chinook Salmon	21	21	9	13	13	23
Non-chinook Salmon	23	23	8	11	11	24

Note:
APICDA—Aleutian Pribilof Island Community Development Association.
BBEDC—Bristol Bay Economic Development Corporation.
CBSFA—Central Bering Sea Fishermen's Association.
NSEDC—Norton Sound Economic Development Corporation.
YDFDA—Yukon Delta Fisheries Development Association.
BS—Bering Sea.
AI—Aleutian Islands.
WAI—Western Aleutian Islands.
CAI—Central Aleutian Islands.
EAI—Eastern Aleutian Islands.

Dated: September 9, 1998.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–24725 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 63, No. 179

Wednesday, September 16, 1998

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1726

Revision of Electric Program Standard Contract Forms

AGENCY: Rural Utilities Service, USDA.

ACTION: Advanced Notice of Proposed Rulemaking.

SUMMARY: The Rural Utilities Service (RUS) requires borrowers to use standard forms of contracts promulgated by RUS when contracting for construction, procurement, engineering services, or architectural services financed through loans made or guaranteed by RUS, in accordance with applicable RUS regulations. RUS is planning to update, consolidate, and streamline the standard forms of contracts used for construction and procurement.

DATES: Written comments must be received by RUS, or bear a postmark or equivalent, no later than November 16, 1998.

ADDRESSES: Written comments should be addressed to F. Lamont Heppe, Jr., Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, Stop 1522, 1400 Independence Avenue, SW., Washington, DC 20250–1522. Telephone: (202) 720–9550. RUS requires a signed original and three copies of all comments (7 CFR 1700.4). Comments will be available for public inspection during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Fred J. Gatchell, Deputy Director, Electric Staff Division, Rural Utilities Service, U.S. Department of Agriculture, Stop 1569, 1400 Independence Ave., SW., Washington, DC 20250–1569. Telephone: (202) 720–1398. FAX: (202) 720–7491. E-mail: fgatchel@rus.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The standard loan agreement between RUS and its electric borrowers provides that, in accordance with applicable RUS regulations, the borrower shall use standard forms of contracts promulgated by RUS for construction, procurement, engineering services, and architectural services financed by a loan made or guaranteed by RUS. RUS also publishes forms of contracts which serve as guidance to borrowers and which borrowers may use at their discretion. RUS is planning to update, consolidate, and streamline the standard forms of contracts used for construction and procurement. The forms included in this effort are:

Primary Contract Forms

1. RUS Form 198, Rev. 2–95, Equipment Contract. This form is used for equipment purchases.
2. RUS Form 200, Rev. 2–95, Construction Contract—Generating. This form is used for generating plant construction or for the furnishing and installation of major items of equipment.
3. RUS Form 201, Rev. 2–95, Right-of-Way Clearing Contract. This form is used for distribution line right-of-way clearing work, which is to be performed separate from line construction.
4. RUS Form 203, Rev. 2–95, Transmission System Right-of-Way Clearing Contract. This form is used for transmission right-of-way clearing work, which is to be performed separate from line construction.
5. RUS Form 257, Rev. 2–95, Contract to Construct Buildings. This form is used to construct headquarters buildings and other structure construction.
6. RUS Form 764, Rev. 2–95, Substation and Switching Station Erection Contract. This form is used to construct substations and switching stations.
7. RUS Form 786, Rev. 2–95, Electric System Communications and Control Equipment Contract. This form is used for delivery and installation of equipment for system communications.
8. RUS Form 790, Rev. 2–95, Distribution Line Extension Construction Contract (Labor and Materials). This form is used for limited distribution construction accounted for under work order procedure.
9. RUS Form 792, Rev. 2–95, Distribution Line Extension Construction Contract (Labor Only). This form is used for limited distribution construction accounted for under work order procedure.
10. RUS Form 830, Rev. 2–95, Electric System Construction Contract (Labor and Materials). This form is used for distribution and transmission line project construction.
11. RUS Form 831, Rev. 2–95, Electric Transmission Construction Contract (Labor and Materials). This form is used for transmission line project construction.

Other Contract Forms

1. RUS Form 168b, Rev. 2–95, Contractor's Bond. This form is used to obtain a surety bond and is included in RUS Forms 200, 201, 203, 257, 764, 786, 790, 792, 830, and 831.
2. RUS Form 168c, Rev. 2–95, Contractor's Bond (less than $1 million). This form is used in lieu of RUS Form 168b to obtain a surety bond when contractor's surety has accepted a Small Business Administration guarantee.
3. RUS Form 180, Rev. 2–95, Construction Contract Amendment. This form is used to amend distribution line construction contracts.
4. RUS Form 181, Rev. 2–95, Certificate of Completion, Contract Construction for Buildings. This form is used for the closeout of RUS Form 257.
5. RUS Form 187, Rev. 2–95, Certificate of Completion, Contract Construction. This form is used for the closeout of and is included in RUS Forms 200, 203, 764, 786, 830, and 831.
6. RUS Form 213, Rev. 2–95, Certificate (''Buy American''). This form is used to document compliance with the ''Buy American'' requirement.
7. RUS Form 224, Rev. 2–95, Waiver and Release of Lien. This form is used for the closeout of and is included in RUS Forms 200, 203, 764, 786, 830, and 831.
8. RUS Form 231, Rev. 2–95, Certificate of Contractor. This form is used for the closeout of and is included in RUS Forms 200, 203, 764, 786, 830, and 831.
9. RUS Form 238, Rev. 2–95, Construction or Equipment Contract Amendment. This form is used to amend contracts except distribution line construction contracts.
10. RUS Form 251, Rev. 2–95, Material Receipt. This form is used to document receipt of owner furnished

materials and is included in RUS Forms 764, 830, and 831.

11. RUS Form 254, Rev. 2–95, Construction Inventory. This form is used for the closeout of RUS Forms 203, 764, 830, and 831. This form is available from RUS.

12. RUS Form 307, Rev. 2–95, Bid Bond. This form is used to obtain a bid bond and is included in RUS Forms 200, 203, 257, 764, 830, and 831.

13. RUS Form 792b, Rev. 2–95, Certificate of Construction and Indemnity Agreement. This form is used for the closeout of and is included in RUS Forms 201, 790, 792.

14. RUS Form 792c, Rev. 2–95, Supplemental Contract for Additional Project. This form is used to amend and is included in RUS Forms 201, 790, 792.

Guidance Forms

1. RUS Form 172, Rev. 9–58, Certificate of Inspection, Contract Construction. This form is used to notify RUS that construction is ready for inspection.

2. RUS Form 173, Rev. 3–55, Materials Contract. This form is used for distribution, transmission, and general plant material purchases.

3. RUS Form 274, Rev. 6–81, Bidder's Qualifications. This form is used to document bidder's qualifications.

4. RUS Form 282, Rev. 11–53, Subcontract. This form is used for subcontracting.

5. RUS Form 458, Rev. 3–55, Materials Contract. This form is used to obtain generation plant material and equipment purchases not requiring acceptance tests at the project site.

Our plans for revising and updating these forms include:

1. Eliminate unneeded forms. This would include merging the Form 181 into the Form 187, merging the Form 180 into the Form 238, merging the Form 201, 203, and 764 into the Form 830, and eliminating Forms 181, 180, 201, 203, and 764. We are also considering eliminating infrequently used guidance forms (Forms 172, 173, 274, 282, and 458.)

2. Make forms suitable for ''subject to'' or ''not subject to'' RUS approval. This would include merging the Form 831 into the Form 830 and eliminating Form 831.

3. Make construction contract forms suitable for ''labor only'' or ''labor and material.'' This would include merging the Form 792 into the Form 790 and eliminating Form 792.

4. Standardize tables and information pages and incorporate them as separate attachments. We are considering publishing the ''Construction Units'' pages as a separate bulletin. This would allow the borrower to include in the bid package only those construction unit pages that are relevant to a particular project.

5. Maximize consistency among forms. This would include standardizing common provisions and terminology, and adding a ''Notice and Instructions to Bidders'' to forms not having one.

6. Include an estimated or base quantity provision in unit price contract forms.

7. Add a provision regarding assignment of the contract to RUS.

8. Update and clarify contract provisions as necessary. This would include:

a. Clarifying that the contractor (not the owner or engineer) is solely responsible for the means and methods of construction and for the supervision of the contractor's employees.

b. Deleting the reference to a ''Supervisor'' appointed by RUS.

c. Delete the reference to the loan contract and owner's access to funding.

d. Deleting the option for eliminating retainage after the contract is 50 percent complete.

e. Updating the ''Buy American'' requirement.

f. Eliminating gender specific terms (him, his, materialmen, etc.)

RUS invites comments from the public about our plans to update, consolidate, and streamline the standard forms of contracts listed above. We are specifically interested in comments on the following questions:

- Are the guidance forms used often or should they be eliminated?
- Are there provisions in the contract forms that should be updated (in addition to the provisions indicated above)?
- Does the proposed revision/consolidation plan meet the needs of most borrowers?

Dated: September 9, 1998.

Inga Smulkstys,

Acting Under Secretary, Rural Development.

[FR Doc. 98–24763 Filed 9–15–98; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1755

RIN 0572–AB41

Telecommunications System Construction Contract and Specifications

AGENCY: Rural Utilities Service, USDA.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Rural Utilities Service (RUS) is considering possible revisions that may be desirable in form and content of RUS Contract Form 515, Telephone System Construction Contract. This action will amend the Telephone System Specifications which include RUS Bulletin 345–150, Specifications and Drawings for Construction of Direct Buried Plant (Form 515a); RUS Bulletin 345–151, Specifications and Drawings for Conduit and Manhole Construction (Form 515c); RUS Bulletin 345–152, Specifications and Drawings for Underground Cable Installation (Form 515d); RUS Bulletin 345–153, Specifications and Drawings for Construction of Pole Lines, Aerial Cables and Wires (Form 515f); and RUS Bulletin 345–154, Specifications and Drawings for Service Entrance and Station Protector Installation (Form 515g). Changes to the Telephone System Construction Contract and Specifications will incorporate the latest technology, remove redundant or outdated requirements, and simplify the specification format.

DATES: Written comments must be received by RUS, or bear a postmark or equivalent, no later than December 15, 1998.

ADDRESSES: Comments should be mailed to Charlie I. Harper, Jr., Chief, Outside Plant Branch, Telecommunications Standards Division, Rural Utilities Service, STOP 1598, United States Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–1598. RUS requests an original and three copies of all comments (7 CFR part 1700.4). All comments received will be available for public inspection at room 2835 South Building (above address) during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Charlie I. Harper, Jr., Chief, Outside Plant Branch, Telecommunications Standards Division, Rural Utilities Service, STOP 1598, United States Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–1598. Telephone: (202) 720–0680. Fax: (202) 720–4099.

SUPPLEMENTARY INFORMATION: The Telephone System Construction Contract and Specifications are used by borrowers of RUS funds to secure the services of a contractor for the construction of telecommunications facilities. The present form of the contract and specifications has not been

revised since January 1990. RUS is requesting comments from borrowers, consulting engineers, contractors, and other interested parties on recommended changes to the contract form and specifications.

Dated: September 9, 1998.

Inga Smulkstys,

Acting Under Secretary, Rural Development.

[FR Doc. 98–24764 Filed 9–15–98; 8:45 am]

BILLING CODE 3410–15–M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

RIN 3150–AG00

Physical Protection for Spent Nuclear Fuel and High-Level Radioactive Waste: Technical Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations concerning physical protection of spent nuclear fuel and high-level radioactive waste stored at independent spent fuel storage installations, monitored-retrievable storage installations, and geologic repository operations areas. This action is necessary to correct the inappropriate inclusion of surveillance/assessment and illumination systems within the requirement for tamper indication and line supervision.

DATES: Comments must be received on or before October 16, 1998.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Copies of any comments received may be examined at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). From the home page, select ''Rulemaking'' from the tool bar. The interactive rulemaking website can then be accessed by selecting ''New Rulemaking Website.'' The site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905, e-mail cag@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Barry Mendelsohn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7262.

SUPPLEMENTARY INFORMATION: For additional information see the Direct Final Rule published in the Rules and Regulations section of this **Federal Register**.

Because NRC considers this action noncontroversial, we are publishing this proposed rule concurrently with a direct final rule. The direct final rule will become effective on November 12, 1998. However, if the NRC receives significant adverse comment on the direct final rule by October 16, 1998, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the direct final rule in a subsequent final rule. The NRC will not initiate a second comment period for this action in the event the direct final rule is withdrawn.

Environmental Impact: Categorical Exclusion

The Commission has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22 (c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval number 3150–0002.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

A regulatory analysis has not been prepared for this proposed rule because this rule is considered corrective in nature and a minor, nonsubstantive amendment; it has no adverse economic impact on NRC licensees or the public.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1989, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant impact upon a substantial number of small entities. The regulation would affect entities licensed to operate independent spent fuel storage installations, monitored-retrievable storage installations, and geologic repository operations areas. These entities do not fall within the definition of small entities.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this rule, and therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

List of Subjects in 10 CFR Part 73

Criminal penalties, Hazardous materials transportation, Exports, Imports, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendment to 10 CFR Part 73.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C, 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99–399, 100 Stat. 876 (42 U.S.C. 2169).

2. Section 73.51(d)(11) is revised to read as follows:

§ 73.51 Requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste.

* * * * *

(d) * * *

(11) All detection systems and supporting subsystems must be tamper indicating with line supervision. These systems, as well as surveillance/assessment and illumination systems, must be maintained in operable condition. Timely compensatory measures must be taken after discovery

of inoperability, to assure that the effectiveness of the of the security system is not reduced.

* * * * *

Dated at Rockville, Maryland, this 26th day of August, 1998.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 98–24716 Filed 9–15–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300 and 1310

[DEA Number 137P]

RIN 1117–AA31

Exemption of Chemical Mixtures

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: The DEA is proposing regulations to implement those portions of the Domestic Chemical Diversion Control Act of 1993 [Pub. L. 103–200] (DCDCA) that exempt from regulation under the Controlled Substances Act (CSA) certain chemical mixtures that contained regulated chemicals. The DCDCA amended the CSA to require that only those chemical mixtures identified by regulation shall be exempt from application of DEA's regulatory controls. These proposed regulations identify those mixtures, or categories of mixtures, that will be exempt from regulation. This proposal also defines an application process that can be used to exempt chemical mixtures that do not meet the criteria for automatic exemption.

DATES: Written comments or objections must be submitted on or before November 16, 1998.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7138.

SUPPLEMENTARY INFORMATION: The Chemical Diversion and Trafficking Act of 1998 (PL 100–690) (CDTA) was passed by Congress to curtail the diversion of specific chemicals used in the illicit manufacture of controlled substances. The CDTA established recordkeeping and reporting requirements necessary for DEA to identify and track chemical diversion. While the CDTA achieved initial success in curtailing the diversion of chemicals, traffickers soon found and took advantage of certain shortcomings in the law. In the United States (U.S.), traffickers were able to obtain needed supplies by purchasing products that were exempted from regulation under the CDTA. Foreign traffickers were able to obtain chemicals from sources outside the U.S., while taking advantage of U.S. brokers and traders because of these shortcomings. Additionally, taking action against unscrupulous suppliers proved difficult.

To address the weaknesses in the CDTA, Congress passed the Domestic Chemical Diversion Control Act of 1993 (DCDCA), which was enacted in April of 1994. One provision of the DCDCA dealt with the exemption of chemical mixtures, which are defined as ''a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.''

Prior to the enactment of the DCDCA, the term regulated transaction was defined to exclude 'any transaction in a chemical mixture' (21 U.S.C. 802 (39)(A)(v)). Therefore, transactions involving all chemical mixtures were exempt from recordkeeping and other chemical regulatory control requirements of the CSA. This exemption provided traffickers with an unregulated source for obtaining chemicals for use in the manufacture of controlled substances. Furthermore, this exemption was inconsistent with the requirements of Article 12, Paragraph 14 of the United Nations 1988 Convention on Psychotropic Substances. Article 12 states, in part, that ''The provisions of this article shall not apply to pharmaceutical preparations, nor to other preparations containing substances in Table I or Table II that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means''. To address these problems, the DCDCA amended the exemption to provide that only those chemical mixtures specified by regulation would be exempt.

The DCDCA amended the definition of a regulated transaction to exclude only those mixtures which the Attorney General has by regulation designated as exempt. This designation is ''based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered''. Accordingly, with this proposal, the DEA is seeking to enact regulations that prevent diversion of mixtures which contain listed chemicals, while removing from the regulatory scheme mixtures which meet the above legal criteria [21 U.S.C. 802(39)(A)(v)].

Chemical mixtures which contain listed chemicals are of concern to DEA if they can be used in the manufacturing of controlled substances. Laboratory operators have continually searched for unregulated sources of materials in their efforts to illegally manufacture controlled substances. These efforts have led to the diversion and illicit utilization of chemical mixtures.

Chemical mixtures can and do play a role in the illicit production of controlled substances such as heroin, cocaine and amphetamine related compounds, including methamphetamine. Some examples follow.

The chemicals used in the production of cocaine are included primarily on list II of the CSA. Suspicious shipments of mixtures containing solvents in list II to cocaine producing areas have been identified by DEA. Additionally, diversion of such chemical mixtures for the illicit production of cocaine in foreign countries has been established by DEA. DEA continually monitors the chemical composition of seized cocaine hydrochloride. The DEA laboratory system is able to detect the trace quantities of solvents present in seized cocaine hydrochloride. Such solvents are utilized in the final stage of cocaine production whereby cocaine base is converted to cocaine hydrochloride. Recent data indicate that a broader range of solvents and solvent combinations are being caused in cocaine processing. This laboratory data supports intelligence information that chemical mixtures are used in the production of cocaine hydrochloride.

Chemical mixtures also play a role in the production of methamphetamine, the most prevalent controlled substance illicitly synthesized in the United States. During calendar years 1994 through 1997, the DEA was involved in the domestic seizure of over 2,800 clandestine methamphetamine laboratories. The chemicals ephedrine and/or pseudoephedrine were utilized as the precursor material at the vast majority of these laboratories.

The clandestine manufacture, distribution and abuse of methamphetamine are serious public

health problems. Nationally, the Drug Abuse Warning Network (DAWN) has documented approximately 2,900 methamphetamine/speed related deaths in the United States between January 1992 and December 1996.

Despite considerable efforts by Federal, state and local law enforcement, the illicit production, distribution and abuse of methamphetamine continue. Recent DEA seizure statistics indicate that the number of methamphetamine laboratory seizures has increased dramatically in 1996 and 1997. During 1997, the DEA participated in more than 1,400 methamphetamine laboratory seizures. This figure does not take into account the many laboratory seizures conducted independently by state and local law enforcement agencies. The problem continues into 1998.

During the 1970's and early 1980's, P2P was the primary precursor used in the clandestine production of methamphetamine in the U.S. P2P was controlled as a Schedule II controlled substance in 1980 through the administrative provision authorizing control of immediate precursors under the CSA (21 U.S.C. 811(e)). In an attempt to circumvent the control of P2P, traffickers sought P2P in unregulated international markets and resorted to the manufacture of P2P in clandestine laboratories utilizing phenylacetic acid and acetic anhydride.

In the middle 1980's, U.S. clandestine laboratory operators began utilizing the ephedrine reduction method of manufacturing methamphetamine. Since ephedrine was unregulated at the time, most laboratory operators abandoned the P2P method and instead moved to the use of bulk ephedrine powder as their source of precursor material.

The Chemical Diversion and Trafficking Act of 1988 (CDTA) modified the Controlled Substances Act (CSA) to give DEA authority to exercise regulatory control of the chemicals used for the refinement and synthesis of illicitly manufactured controlled substances. The CDTA imposed recordkeeping, reporting, and import/export notification requirements for regulated transactions of listed chemicals in order to prevent the diversion of these chemicals to the illicit manufacture of controlled substances. The CDTA included bulk ephedrine and pseudoephedrine as listed chemicals.

However, under the CDTA, products containing a listed chemical which were marketed or distributed lawfully under the Federal Food, Drug, and Cosmetic Act were exempt from the CSA's chemical regulatory control provisions. This included over-the-counter (OTC) products which contained ephedrine and pseudoephedrine. Clandestine laboratory operators soon learned that they could obtain the needed precursor materials through the unregulated purchase of millions of dosage units of single-entity OTC ephedrine products.

This loophole in the law was closed by the passage of the Domestic Chemical Diversion Control Act (DCDCA) which became effective on April 16, 1994. This Act further amended the CSA and removed the exemption for those transactions involving products which are marketed or distributed lawfully under the Federal Food, Drug, and Cosmetic Act, if these products contain ephedrine as the only active medicinal ingredient. Thus, single entity ephedrine products became subject to the chemical regulatory control requirements of the CSA.

In response to these actions taken against OTC ephedrine products, clandestine laboratory operators again attempted to circumvent CSA chemical controls in an effort to obtain precursor material. The search for unregulated source of precursor material led to the diversion and illicit utilization of OTC pseudoephedrine products and combination OTC ephedrine products. In response, the Comprehensive Methamphetamine Control Act of 1996 placed regulatory controls on the sale and distribution of such OTC products.

Today, the vast majority (approximately 97 percent) of U.S. clandestine laboratories continue to utilize ephedrine and/or pseudoephedrine as the precursor material. At practically all of these laboratories, the precusor material was obtained via the diversion of ephedrine or pseudoephedrine products marketed in tablet and capsule form and was not obtained through the diversion of bulk powder.

While the vast majority of products seized at illicit methamphetamine laboratories were OTC drug products, dietary supplement products containing ephedrine and/or pseudoephedrine (i.e ephedra) have been seized at clandestine methamphetamine laboratories. At this time, the frequency with which these products are encountered is small. However, DEA studies indicate that the ephedrine/pseudoephedrine contained in this material can be readily recovered and ephedra material can be easily used in the production of methamphetamine. Ephedra (in the form of dietary supplements or ephedra extract), therefore, can and is being used as the source of precursor material for the illicit production of methamphetamine.

Regulation of chemical mixtures is appropriate to guard against their diversion if the products are not formulated in such a way that: (1) they cannot be easily used in the illicit production of a controlled substance; or (2) the listed chemicals cannot be readily recovered. The DCDCA provides DEA with the means to regulate the mixtures and yet allows enough flexibility to ensure that the impact of the regulations can legitimate commerce is minimized.

Regulations regarding the exemption of chemical mixtures were initially proposed by DEA on October 13, 1994 (59 FR 51888). In response to industry concerns, the proposed regulations regarding the exemption of chemical mixtures were withdrawn on December 9, 1994 (59 FR 63738). Between withdrawal of the proposed regulations regarding the exemption of chemical mixtures and the publication of this action as a final rule, all transactions involving chemical mixtures as defined in 21 U.S.C. 802(40) remain exempt from the definition of regulated transaction under the CSA. Based on the discussions and input from industry, DEA is proposing new regulations regarding the exemption of chemical mixtures.

Following withdrawal of the initial proposal, DEA solicited input from, and engaged in discussions with, organizations representing the manufacturers and distributors of products containing listed chemicals. DEA met with representatives from associations (and affiliated members) representing chemical manufacturers, the paint and coating industry, flavor and fragrance manufacturers, chemical distributors and the dietary supplements industry. These different groups expressed unique concerns that the DEA attempted to address within this notice. More recently, however, the DEA has become aware of additional concerns raised by other segments of the affected industries including the dietary supplement industry. While DEA has received input from several associations and firms within these industries, because of the diversity of these industries, the DEA believes that others may have information that the DEA should consider. The DEA is therefore soliciting input from all sectors of the chemical and dietary supplements industry potentially affected by this proposed rulemaking. The DEA recognizes that there may be situations within unique segments of one or more of the affected industries which may not be specifically addressed in this

proposed rulemaking. These may involve products which are not automatically exempt and entities which would not likely be sources of diversion since their products cannot be easily used in the illicit production of a controlled substance or the listed chemicals, which they contain, cannot be readily recovered. In the event that not all exemption provisions for chemical mixtures are included, specific mixtures can be exempted by an application process. The application process is designed to exempt those chemical mixtures that are not automatically exempted under this proposal, but meet the criteria of Title 21 U.S.C. 802(39)(a)((v). As described below, these are processes which individual firms can use to apply for exemption from some or all regulatory controls.

One of the potentially affected industries is the dietary supplement industry which markets non-drug products containing ephedrine/pseudoephedrine. DEA has recently received information from a coalition of direct marketers of these dietary supplements regarding the perceived impact of the proposed regulations on their industry. The principal concern of the direct marketers is how the chemical registration, recordkeeping, reporting requirements may affect those individuals engaged in the direct marketing of the products to the public. DEA emphasizes that it does not foresee the need for the regulation of individuals engaged in the direct marketing of the products to the public, provided certain basic conditions are met. This is consistent with the established intent of the Comprehensive Methamphetamine Control Act of 1966 (MCA) with respect to OTC drug products. While the MCA placed certain regulatory controls on the sale and distribution of pseudoephedrine, phenylpropanolamine and combination ephedrine drug products, it went to great lengths to ensure continued public access to these products at the retail level for face-to-face transactions.

Correspondingly, DEA is proposing in this notice a process by which manufacturers may request exemption for their products. Additionally, DEA can exempt a category of transaction from regulation if it is determined to be unnecessary for enforcement of the CSA (21 U.S.C. 802(39)(a)(iii)) and can exempt any manufacturers or distributors, from the registration requirement if it is consistent with the public health and safety (21 U.S.C. 822(d)). DEA has already received and responded favorably to a request from a direct marketing organization of regulated drug products, excluding the individual marketers from regulations and requiring only that the wholesale activities be regulated. The information submitted by the coalition regarding the manner in which their dietary supplement products are marketed does not to be significantly different from the manner in which these OTC drug products are distributed.

Listed chemicals cover a wide sector of industry because of their varied uses. Some are routinely utilized in legitimately produced chemical formulations while others are not. The DEA has attempted to better understand the degree with which specific listed chemicals are formulated in chemical mixtures that are legitimately produced. An accurate assessment has proved difficult for various reasons. One reason is that, although some examples of formulated products were made available, many manufacturers either did not have this information or were reluctant to discuss their formulations due to concerns regarding the disclosure of trade secrets. Another reason is that chemical mixtures are used in a wide variety of industrial sectors. A complete assessment would involve many diverse sectors such as those involved in paints, coatings, plastics, refineries, and other industrial processes. Additionally, many chemical mixtures are intended for human consumption. These include food and dietary supplements, food additives, flavorings and fragrances.

After careful consideration of the available information, including the input from the chemical industry, DEA is proposing a three-tiered approach to the exemption of chemical mixtures. This approach best captures those chemical mixtures that are ''formulated in such a way that they cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered'', in accordance with Title 21 U.S.C. Section 802 (39)(A)(v). A mixture will be exempt if: (1) it contains a listed chemical at or below an established concentration limit; or (2) it falls within a specifically defined category; and (3) the manufacturer of the mixture applies for and is granted a specific exemption for the product.

I. Concentration Limits

DEA is proposing to use a system of concentration limits as the primary means to determine the regulatory status of chemical mixtures. The use of such a quantitative system is necessary due to the complexity of chemical-based commodities and the huge variety of products. The use of a narrative approach is too subjective and would be in danger of inconsistent interpretation, both by industry and DEA. Use of the concentration limit eliminates subjective interpretation; if the amount of listed chemical in a mixture is less than, or equal to, the concentration limit, then the mixture is exempt.

The concentration of a chemical in a mixture can be determined by either volume or weight, depending on the physical state of the mixture. It is more common to determine the concentration of a solid or gas based on weight, as this more accurately reflects the relative amounts of components in the mixture. The relative amount of a solid or gas in a mixture may not be accurately reflected if based on volume because the weight may change disproportionally relative to volume. The volume is commonly used to determine concentration in liquid—liquid mixtures. For listed chemicals that are liquids, the volume is proposed to be used in determining concentration. The density parameter allows for easy conversion between volume and weight for liquids. Concentration limits are proposed to be determined by weight if the listed chemical exist as a solid or gas at ambient temperature. The weight of the free base or acid will be used to determine the concentration of a listed chemical if it is a salt. A mixture is exempt if the listed chemical or chemicals are less than or equal to the percentages and other conditions described in the ''Table of Concentration Limits.''

Where a mixture contains more than one listed chemical, determining the concentration limit will depend on the properties of the chemicals included in the mixture. Some chemicals, such as the different solvents, are cumulative, i.e., the concentration of the mixture will be determined by adding the concentrations of each individual solvent in the mixture. This approach is necessary when chemicals can be interchanged to carry out an illicit manufacturing procedure. The combined volume of two or more such chemicals would be functionally equivalent to the same volume of either one of the chemicals. If the chemicals are not cumulative, then the concentration of each chemical is considered individually in determining if the mixture is regulated. Those chemicals that are cumulative are identified in the ''Table of Concentration Limits'' in the proposed new Section 1310.12(c).

List I Chemicals

The DEA proposes that N-acetylanthranilic acid, anthranilic acid,

benzyl cyanide, ethylamine, hydriodic acid, 3 4-methylenedioxyphenyl-2-propane, methylamine, nitroethane, phenylacetic acid, piperidine, piperonal, propionic anhydride, isosafrole and safrole have a concentration limit of 20 percent. List I chemicals are used as precursors with the exception of hydriodic acid which is a reagent in the production of controlled substances. These chemicals are extremely valuable to traffickers and, in concentrations of greater than 20 percent, represent a viable source of material for the illegal manufacture of controlled substances. The concentration limit proposed by the DEA takes into consideration the information supplied by the private sector and DEA concerns. The 20 percent limit for these chemicals maintains exemption status for chemical mixtures that are not likely to be diverted while excluding from regulation the majority of the present commerce in these mixtures, as identified by DEA. Safrole and isosafrole are sufficiently similar precursors when used clandestinely, that they will be cumulative. DEA is proposing the following concentration limits for the remaining List I chemicals:

Ephedrine and Pseudoephedrine—2 Percent

Combinations of ephedrine and pseudoephedrine will be cumulative because these two chemicals are completely interchangeable as precursors in the same reaction to make methamphetamine and methcathinone. Thus, if the total concentration of ephedrine and pseudoephedrine is greater than 2 percent, the mixture is treated by DEA as a regulated chemical.

Ephedrine and pseudoephedrine are major precursors for clandestine mathamphetamine and methcathinone production. As previously noted, clandestine laboratory operators have migrated to unregulated sources of precursor material. This has led to the diversion of marketed tablet and capsule pharmaceutical products containing ephedrine and pseudoephedrine. While OTC drug products have been a major source for these chemicals in clandestine laboratories, DEA has also identified non-drug products (i.e. ephedra extracts and dietary supplements) in seized laboratories.

Regulations pertaining to OTC drug products containing ephedrine and pseudoephedrine have been established under separate rulemaking. Non-drug products, including dietary and nutritional supplements are chemical mixtures and therefore shall be subject to these proposed provisions.

Representatives of retail sectors from the dietary and nutritional supplement industry have represented that their products contain amounts consistent with those found in most natural sources. The 2 percent limit has been deliberately proposed at a level greater than the concentrations found in most natural sources. Representatives of the dietary and nutritional supplement retail industry have represented in meetings that the proposed concentration limit would be adequate, however, DEA has subsequently become aware of concerns from other, previously unidentified segments of the dietary and nutritional supplement industry that the proposed regulations could have a significant impact on their operations. This new information revealed that the proposed limit may not be appropriate to exempt certain distributions from the regulatory process.

Of great concern to DEA, however, is the seizure of dietary supplements and ephedra bulk material at clandestine laboratories. Some of this seized material has been found to contain concentrations as low as 3 to 4 percent ephedrine/pseudoephedrine. The 2 percent threshold would therefore capture such material.

Under this proposal, products and material containing less than 2 percent would be automatically exempt. Additionally, harvested plant material will be exempt provided that it is unaltered from its natural state. Manufacturers of products containing greater than 2 percent would be able to apply for exemption based on the criteria in 21 U.S.C. 802(39)(A)(v). In meetings with dietary supplement firms and association, the DEA has requested information on the specific types, composition and volume of dietary supplement products in the marketplace. Responses to these inquires have been sparse.

The 2 percent concentration threshold was established in the consideration of a single entity product containing ephedrine/pseudoephedrine and combination products from which ephedrin/pseudoephedrine can be easily removed. It is likely that multiple ingredient products containing higher concentrations of ephedrin/pseudoephedrine may, in fact, be more difficult to use in the clandestine synthesis of methamphetamine. As such, these products would likely qualify for exemption.

To ensure that DEA has all possible information regarding both the extent and volume of this industry and the impact of any regulations on it, DEA is requesting comments from interested persons who market products that contain ephedrine and/or pseudoephedrine (either as dietary/nutritional supplements or as other products). Comments should identify the type of industry, including the number of companies/individuals involved and the annual volume of business they conduct; how the proposed regulatory requirements would impact that industry, (through the registration, recordkeeping, and reporting requirements), and within the confines of statutory requirements, any suggestions or comments on how the final regulations might better be tailored to the industry without compromising the basic mandate of the law to prevent the diversion of ephedrine and pseudoephedrine for the illicit manufacture of controlled substances.

The DCDCA initiated provisions for the regulatory control of chemical mixtures. However, the DCDCA included exemption provisions for chemical mixtures formulated in such a way that they cannot be easily used in the illicit production of a controlled substance and the listed chemical or chemicals contained in the mixture cannot be readily recovered. Accordingly, if a dietary supplement or any other formulations meet the exemption criteria, these chemical mixtures will receive exemption status. Therefore, the dietary and nutritional supplement industry is requested to provide information as to the nature of these products in relation to the exemption criteria and specify any unique attributes such as formulation, composition, or method of distribution which would prevent diversion for illicit uses. Additionally, the DEA invites comments in response to its concerns regarding the seizure of dietary supplements and ephedra bulk material at clandestine laboratories and the potential expanded role that these products may play in the illicit production of methamphetamine.

Norpseudoephedrine/Phenylpropanolamine—0.6 Percent

N-methylephedrine/N-Methylpseudoephedrine—0.1 Percent

In each set of the above chemical pairs, the chemicals are interchangeable in the clandestine synthesis of controlled substances. Therefore, the concentration limit is proposed to be determined by adding the concentration of each chemical in the pair.

These chemicals can be used in the manufacture of amphetamine and methamphetamine. Commercially, they are used in the manufacture of drug products and can appear in dietary and

nutritional supplements. As with ephedrine and pseudoephedrine, the limits are set higher than concentrations found in most natural sources, even when paired. Therefore, the limit should not affect the dietary and nutritional supplement products.

Benzaldehyde—30 Percent

Benzaldehyde is used for the clandestine manufacture of amphetamine and methamphetamine. DEA has identified it as being widely used in flavoring and as a source of derivatives.

Mixtures containing more than 30 percent benzaldehyde can be readily used in clandestine synthesis, especially when the other chemicals are solvents. This is also true when benzaldehyde is mixed with several other chemicals if those additional chemicals are not reactive in the synthetic pathways used to manufacture illicit substances. DEA is aware that this concentration limit may not capture most mixtures, especially with respect to flavoring and fragrance products. However, with the increasing effectiveness of the chemical controls against the diversion of other amphetamine/methamphetamine source materials, the potential for diversion of benzaldehyde, including mixtures, may increase significantly. The DEA is interested in soliciting comments from interested persons involved with chemical mixtures containing benzaldehyde. For products which contain greater than 30 percent benzaldehyde, the proposal establishes an application process by which individual or group exemptions can be obtained.

Ergonovine and Ergotamine—No Concentration Limit

DEA is proposing to regulate all mixtures containing ergonovine and ergotamine. The natural concentrations of these chemicals is on the order of a few hundredths of a percent. The alkaloids are precursors for the manufacture of hallucinogens that are potent in microgram dosages; little material is required to manufacture viable quantities of illicit drugs. Commercially, these chemicals are only found in prescription drug products, which are already exempt; therefore their regulation in chemical mixtures should not have any impact.

List II Chemicals

List II chemicals, while not precursors of the controlled substances, are essential for carrying out the illegal manufacture of controlled substances. DEA is proposing the following concentration limits for List II chemicals:

Acetone, Methyl Ethyl Ketone (MEK), Methyl Isobutyl Ketone (MIBK), Toluene, and Ethyl Ether—35 Percent

These chemicals are interchangeable and also are effective when used in combination in clandestine operations; therefore, they are cumulative.

These solvents are used, either singly or in combination, in the processing of cocaine hydrochloride. Commercially, they are used in a wide variety of industrial processes and represent the majority of mixtures affected by the chemical regulations. In reviewing the properties of these solvents, DEA has determined that in mixtures with concentrations of greater than 35 percent, either individually or in combination with another solvent, the mixture emulates the properties of the listed solvent. Therefore, the concentration limit for such mixtures is proposed to be 35 percent.

Acetic Anhydride, Benzyl Chloride, Hydrochloric Acid, Iodine and Sulfuric Acid—20 Percent

Potassium Permanganate—15 Percent

These chemicals are used as reagents and precursors in the process of manufacturing controlled substances. Reagents and precursors are typically solutes which are dissolved in a solvent in order for a chemical reaction to be carried out. Because they are dissolved, the amount of listed precursor or reagent needed is less than the amount of listed solvent needed to manufacture a controlled substance. This puts mixtures containing less than the 35 percent concentration limit, as set for solvents, at risk of diversion. Consequently, a 20 percent concentration limit is proposed for these chemicals, except for potassium permanganate, for which the proposed concentration limit is 15 percent. DEA has not identified any mixtures that contain potassium permanganate in concentrations greater than 15 percent.

II. Specific Mixture Categories

While the concentration limits will suffice for the majority of chemical mixtures, there are certain categories of mixtures that fall outside of the limits provided, but are not considered to be likely sources for diversion. DEA has identified three such categories: (1) waste materials regulated by the Environmental Protection Agency (EPA); (2) paints and coatings; and (3) harvested plant material.

(1) Waste mixtures that: (a) are subject to the requirements of 40 CFR Sections 262 and 263.20–22; (b) must be documented on U.S. Environmental Protection Agency Form 8700–22/22A (Uniform Hazardous Waste Manifest); and (c) are being distributed to another person solely for the purpose of disposal by incineration are exempt. These mixtures include only those that are covered by EPA regulations and have a 'cradle to grave' paper trail. Further, the exemption applies only to the extent that the Form 8700–22/22A is available for inspection and copying by DEA. If the generator fails to release, or permit the release, of the necessary information required by DEA, then the mixtures will be treated as a regulated mixture. Finally, any change in the requirements with respect to Form 8700–22/22A, including EPA exemption of a mixture or a waste management site, could result in modification or removal of the exemption.

(2) Completely formulated paints and coatings. DEA recognizes that while paints and coatings, as defined below, may contain a higher concentration of a listed chemical than allowed for exemption, they also contain other ingredients, such as pigments, that render them unsuitable as a source of supply for chemical traffickers.

For purposes of the exemption, a completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable, or mastic composition designed for application to a substrate in a thin layer which is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. A completely formulated paint or coating contains all the components of the paint/coating mixed without the need to add any other material except a thinner for use in the final application. Included in this category are paints, clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks and temporary protective coatings. To qualify for the exemption, a paint or coating must meet the American Society for Testing Materials specifications for the specific product.

(3) Harvested plant material. Harvested plant material that contains listed chemicals, while meeting the definition of chemical mixture, will be exempt provided that the plant material is unaltered from its natural state. Changes in the physical state that preserve the natural composition of the material, such as grining, chopping, mulching, or cutting, do not affect the exemption status. However, changes that alter the natural composition of the material, such as that resulting from chemical or physical extraction, concentrating, enhancement, or by chemical reaction or any such

treatment, will disqualify the mixture from exemption.

III. Exemption By Application

For those chemical mixtures that may not otherwise qualify for an exemption, but are formulated in such a manner that the listed chemicals cannot be readily recovered from the mixture and the mixture itself cannot be used for illicit drug manufacture, DEA is proposing a procedure by which the manufacturer of the mixture may apply for an exemption of the mixture or group of mixtures. The application may be submitted for a single mixture or a group of mixtures containing the same listed chemical at equal concentration with variations in the concentration of the other non-listed chemicals in the mixture. Consideration will also be given to applications for mixtures in which the concentration of the listed chemical varies without regard to the specific concentrations of the other non-listed chemicals in the mixture. In either group, variation of the concentration of any chemical within the mixture that will result in a change in the function of the mixture will disqualify the mixture from the group. The Administrator may determine that a specific mixture does not qualify as part of a group. Each manufacturer must request exemption status for its particular products; exemption of a product for one manufacturer does not carry over to the same or similar products for another manufacturer.

An application for exemption must contain identifying information about the applicant, qualitative and quantitative data regarding the mixture, and justification as to why the mixture should be exempted. DEA may request additional information on the formulation and distribution of the mixture or clarification of any submitted information, as needed. The application for exemption will contain a consent for the termination of exemption by decision of the Administrator upon evidence that the product has been diverted for the use of producing a controlled substance.

Termination of Exemption

The Administrator may terminate or modify the exemption for any chemical mixture that has been granted an exemption if evidence of diversion or attempted diversion is found. Evidence that a chemical mixture has been or is being used in the manufacuturing of a controlled substance will be adequate reason to revoke exemption status for a specific product or all similar chemical mixtures which the DEA determines can be used in the illicit manufacdturing process for which the evidence is obtained.

Procedures are given in this proposed rule for the termination of an exemption granted pursuant to 21 CFR 1310.12 or 1310.13 and differ according to whether removal of exemption status is product specific or by change of any criterion in 21 CFR 1310.12(c) or 1310.12(d). The DEA will issue and publish in the **Federal Register** notification of the termination of exemption of a specific exempt product or group of exempt products for which evidence of diversion has been found. This order shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the notice within 60 days of the date of publication of the order in the **Federal Register**. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until reconsideration of the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate. The DEA shall send written notification to the manufacturer only in instances where the manufacturer of affected products has been readily identified, advising of an action prior to publication in the **Federal Register**.

Trade Secrets

Information required by the DEA to exempt a product includes qualitative and quantitative data for the product. Industry groups expressed concern regarding confidenticality and trade secrets. The DEA has considerable experience in safeguarding trade secrets. The issue of protection of confidential business information has been addressed by the DEA in the **Federal Register** Final Rule published on June 22, 1995 which finalized specific provisions of the DCDCA (60 FR 32453). The release of confidential business information that is protected from disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4) (FOIA), is governed by Section 310 (c) of the CSA (21 U.S.C. 830(c)) and the Department of Justice procedures set forth in 28 CFR 16.7.

Section 310(c) of the CSA provides that information collected under Section 310 that is protected from disclosure under Exemption 4 may only be released in circumstances related to the enforcement of controlled substance or chemical laws, custom laws, or for compliance with U.S. obligations under treaty or international agreements. The Department of Justice procedures establish that if a FOIA request is received for release of information that is protected under Exemption 4, the submitter of the protected information must be notified of such a request, given an opportunity to object to the disclosure and allowed to provide justification as to why the information should not be disclosed.

Regulation of Chemical Mixtures

There are some chemical mixtures that will not meet the proposed exemption criteria and will be subject to regulation. It is proposed that the threshold be determined by taking the entire weight or volume of the regulated mixture for mixtures regulated due to the presence of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene. In mixtures that contain two or more listed chemicals, other than acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene, each chemical shall be compared against its respective threshold. Where the mixture contains two or more chemicals that are cumulative, other than acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene, then the summed concentration of the listed chemicals that are cumulative will be considered; where the total weight of the cumulative listed chemicals exceeds the threshold for any one of the listed chemicals contained in the mixture, then the transaction will be regulated. Thresholds are proposed to be determined by taking the weight or volume of listed chemical contained in the mixture for all other listed chemicals.

Further, the provisions regarding excluded transactions, as set out in 21 CFR 1310.08, will apply equally to mixtures containing the specified chemicals.

Regulatory Flexibility and Small Business Concerns

The Domestic Chemical Diversion Control Act of 1993 replaced the existing blanket exemption from regulation for chemical mixtures with a provision that only those chemical mixtures specifically identified by regulation would be exempt from DEA's chemical controls, based on a finding that each mixture cannot be easily used in the illicit manufacture of a controlled substance and that the chemical(s) contained in the mixtures cannot be readily recovered. This change was necessary to make the U.S.'s chemical controls consistent with Article 12,

Paragraph 14 of the United Nations 1998 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), which requires that chemical controls apply to the chemicals themselves and to products containing the chemicals that are compounded in such a way that such chemicals cannot be easily used or recovered by readily applicable means.

In considering application for the new requirement, DEA recognized that neither regulation nor exemption of all mixtures were a feasible approach. Regulation of all chemical mixtures would cast too broad a net, encompassing products that are not of significant concern to DEA as sources for the diversion of listed chemicals and resulting in an unnecessary regulatory burden on both industry and DEA. Also of significance, exemption of all chemical mixtures would leave products that are suitable for use in the illicit manufacture of controlled substances open for diversion. With the growing effectiveness of chemical controls, such unregulated mixtures could become a significant source of chemicals for diversion, which would be inconsistent with both DEA's mandate and the U.S.'s responsibilities under the 1988 Convention. Therefore, it was necessary to identify some middle ground that would minimize the impact on industry while still satisfying the intent of the requirement and the U.S.'s obligations under the 1988 Convention.

Originally, DEA proposed a system whereby manufacturers would request exemptions for their specific products. However, industry expressed concerns that the administrative burdens, for both industry and DEA, would be too great, given the number of chemical mixtures in commerce. Based on those concerns, DEA withdrew the proposal and opened a dialogue with representative from the manufacturing, distributing, and related segments of the chemical industry regarding how to best address the matter of exemption.

An important DEA objective in establishing exemption criteria was to obtain recommendations from the affected industry. The DEA met with several interested parties including associations representing chemical manufacturers, paint and coatings industry, flavor and extract manufacturing, dietary supplement manufacturers and distributors, and chemical distributors and affiliated members. These discussions, along with available DEA information pertaining to the illicit manufacture of controlled substances, were considered in the establishment of exemption criteria under this proposal. The DEA realizes that, because of the diverse industries affected by these regulations, not all interested persons may have been fully represented prior to the publication of this proposal. The DEA is therefore requesting that comments be submitted to help ensure that the concerns of all interested parties are considered.

Comments should identify the type of industry, including the number of companies/individuals involved and the annual volume of business they conduct; how the proposed regulatory requirements would impact that industry (through the registration, recordkeeping, and reporting requirements), and within the statutory requirements, any suggestions or comments on how the final regulations might better be tailored to the industry without compromising the basic mandate of the law to prevent the diversion of listed chemicals for the illicit manufacture of controlled substances.

The initial concern in addressing the matter of exemption was to establish a system for the identification of the categories of chemical mixtures to be exempted that would be objective and specific enough to allow nontechnical personnel to easily understand and apply the criteria and to allow accurate identification of those mixtures that could readily be used in the illicit manufacture of controlled substances while not encumbering those that could not.

Two options were considered: (1) The used of general product categories, such as paints, coatings, adhesives, and sealants; refinery and chemical plant streams; waste products; insecticides, pesticides, and herbicides; consumer products, including cosmetics; and solutions containing more than 5 percent solids by weight; and (2) the use of concentration limits, expressed as the percentage of chemical, either by volume or weight, that a mixture may contain.

Examination of the use of product categories revealed problems involving their subjective nature, which could lead to confusion regarding whether certain products might be included in the category. In addition, the lack of specificity in such a system would cause difficulties in identifying products that should not be included in a category because of the manner in which they are formulated. It quickly became apparent that use of product categories as the primary means to identify exempt chemical mixtures would require the development of a cumbersome, highly technical, and complicated set of definitions and criteria in order to identify the mixtures to be granted exemption.

The concentration limits, by contrast, provide a clear cut, objective means to identify whether a chemical mixture is or is not exempt. By focusing specifically on the amount of chemical contained in a given amount of mixture, which is of primary concern to DEA, the system provides and unequivocal standard that is easily understood by expert and layman alike. There is no need to establish a large, complex and highly technical set of definitions and crtiera that must be used to make a subjective determinations to what category a mixture belongs in and whether it meets the exemptions criteria or not.

While the system of concentration limits can be used satisfactorily with most chemical mixtures, it does not address those circumstances where the formulation of the mixture or the manner in which the mixture is distributed may be factors for consideration in determining exemption status. Therefore, DEA is proposing the use of certain limited categories for exemption. Additionally, DEA recognizes that there will be those individual products which may not meet the established exemption criteria but are deserving of consideration for exemption due to specific factors that may limit their use in the illicit manufacture of controlled substances. Therefore, provisions have been made in the proposed regulations for a system for which a manufacture may request exemption of a specific mixture.

Once the basic framework for the exemption process had been established, DEA consulted with representatives of the regulated industry, including chemical manufacturers and distributors, as well as the paint and coatings, the flavoring and fragrances, and the dietary and nutritional supplements industries, to identify the concentration limits or other criteria that would satisfy the requirements of the law with the least possible burden on regular commerce. The proposed concentration limits were based on consideration of how useful the mixtures would be in the illicit manufacture of controlled substances and how great a percentage of the mixtures in regular commerce could be exempted from regulation; the proposed limits provide a good balance between the requirements of the law and the need to minimize the impact of the law on legitimate commerce. Representatives of the chemical manufacturers and distributors have indicated that the proposed concentration limits should provide for

exemption of the majority of chemical mixtures in commerce.

In those instances where a chemical mixture will be subject to regulation, the regulatory requirements are not unduly burdensome and should not present any restriction on regular commerce. The primary requirement, recordkeeping, applies only to those transactions that meet or exceed the threshold established for the chemical contained in the mixture. The information required to be maintained in the records is minimal and can usually be found in the normal business records maintained by anyone following good business practices. Additionally, the chemicals contained in the mixture may be subject to other Federal or state recordkeeping requirements, in which case the records maintained may be used to satisfy DEA's requirement, provided the necessary information is readily available. In addition, this proposed rule will exempt persons from registration if the only List I chemicals which they distribute, import or export are contained in exempt mixtures; it is DEA's understanding that the bulk of chemical mixtures in commerce contain List II, rather than List I chemicals.

In summary, the proposed system provides for the exemption of the greatest possible population of mixtures while remaining consistent with the requirements of the law and obligations under the U.N. Convention. The combination of exemptions, together with the threshold system and requirement that registration be obtained only for activities involving List I chemicals allows for the lease possible burden and cost to industry. Therefore the Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small business entities.

With respect to the specific economic and regulatory burdens associated with the regulation of chemical mixtures (in those instances where exemption is not possible), there are three different requirements to be considered:

Registration

This requirement applies solely to persons who distribute, import, or export List I chemicals, including those contained in regulated chemical mixtures. Registration is required on an annual basis. The initial registration cost is $595.00 and the annual registration renewal cost is $477.00. Completion of the application requires approximately 30 minutes.

The impact of the registration requirement will vary depending on the type of industry and type of transactions. As noted, the registration requirement applies only to List I chemicals.

Recordkeeping

Regulated persons must keep records regarding regulated transactions. The records must reflect the name, address, and, if required, DEA registration number of each party to the transaction; the date of the transaction; the name, quantity, and form of packaging of the listed chemical; the method of transfer (company truck, picked up by customer, etc.); and the type of identification used by the purchaser and any unique number on that identification.

As noted in 21 CFR 1310.06(b), normal business records shall be considered adequate for satisfying the recordkeeping requirement, if they contain the required information and are readily retrievable from the other business records of the regulated person. It has been DEA's experience that regulated persons at the non-retail level maintain such information in their normal business records; therefore, no additional burden is considered to apply. At the retail level, such information is not normally kept, therefore, any records to be maintained would have to be considered as part of the regulatory burden.

Reporting

Regulated persons must make reports of any regulated transactions involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the regulations (21 CFR 1310.05(a)(1)). Additionally, any unusual or excessive loss or disappearance of a listed chemical must be reported. It must be emphasized that this requirement does not apply to all sales of listed chemicals; it applies only to those sales involving suspicious/unusual circumstances or thefts/losses.

In addition to the above reporting requirement, the Comprehensive Methamphetamine Control Act of 1996 (MCA) established the requirement that each regulated person who engages in a transaction with a nonregulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing those chemicals) and uses or attempts to use the Postal Service or any private or commercial carrier, shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General (21 U.S.C. 830(b)(3)). This requirement has been the subject of much discussion and it is generally accepted that the manner in which it is written provides DEA with no discretion to exclude any person from the requirement. Legislative amendment of this requirement to allow DEA some measure of discretion in its application is being explored.

Total Regulatory Impact

The total regulatory impact of these requirements will vary based on the type of industry involved and the types of transactions being conducted. With the chemical industry, the total impact should be limited. DEA has been informed by representatives of the chemical industries that the bulk of chemical mixtures will contain List II chemicals. Further, many of the companies that handle List I chemical mixtures are already registered to handle List I chemicals. Therefore, the registration requirement will have limited impact on that industry.

With respect to the recordkeeping requirements, the bulk of the chemical mixture transactions are commercial in nature and involve materials that are subject to stringent Federal and state requirements; the information required to satisfy DEA's recordkeeping requirements will already be available as part of the business records being maintained by the regulated persons. Therefore, no additional burden is anticipated to satisfy the recordkeeping requirement. With respect to reporting, DEA is adjusting its existing, OMB approved information collection regarding Reports of Suspicious Orders or Theft/Loss of Listed Chemicals/ Machines (OMB Number 1117–0024), to increase the estimated number of annual reports by 2,000 and the estimated burden hours by 340 hours per year.

With the dietary and nutritional supplement industry, the issue is somewhat less clear. DEA has been informed by the manufacturers and distributors of products that are sold at retail that their products contain concentrations of ephedrine that are consistent with the proposed exemption limit; therefore, the retail side of the industry should experience little, if any, regulatory impact. However, DEA was recently contacted by representatives of a segment of the industry involved in the direct marketing of these products, who expressed grave concern regarding the potential impact of the requirements on direct marketers, especially the individual marketers selling small

amounts of the product to friends and neighbors.

DEA is well aware of the potential impact that the regulations could have on such operations, having dealt with the issue with respect to the direct marketing of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine. As was stated in the discussion regarding Exemption by Application earlier in this document, it is not the intent of DEA to regulate those individuals engaged in direct marketing sales of small amounts of these products in face-to-face transactions. In addition to the proposed regulations allowing for exemption by application, there are existing exemption procedures available for types of transactions and categories of persons. An exemption has already been provided to one direct marketing organization and discussions are underway with another to also provide an exemption provided certain circumstances are met. It must be noted that the exemptions apply to individuals engaged in direct marketing sales of small amounts of these products in face-to-face transactions; manufacturers and wholesale distributors of the products remain subject to the regulatory requirements.

Assessing the overall impact of the regulations on the dietary and nutritional supplement industry has been hampered by the lack of information regarding the overall scope and population of the industry. DEA has, along with others, requested demographic information from the industry; however, to date, we have not received the details necessary to adequately estimate the potential impact of the regulations. As stated elsewhere in this document, interested persons are invited to submit comments identifying the scope and population of the industry; the effect of the regulations on the industry, both in terms of the extent to which proposed and existing exemptions will exclude the industry from regulation and, where the exemptions do not extend, how the above requirements will impact the industry; and any comments or suggestions on how the regulations might be adjusted to address industry concerns without compromising their intent to prevent the diversion of listed chemicals to the illicit manufacture of controlled substances.

This proposed rule has been reviewed pursuant to Executive Order 12866 and has been determined to be a significant regulatory action. Therefore, it has been reviewed and approved by the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control, Controlled substances, List I and List II chemicals.

21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, it is proposed that 21 CFR parts 1300 and 1310 be amended as follows:

PART 1300—[AMENDED]

1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.02 is proposed to be amended by revising the paragraph (b)(28)(i)(E) to read as follows:

§ 1300.02. Definitions relating to listed chemicals.

* * * * *

(b) * * *

(28) * * *

(i) * * *

(E) Any transaction in a chemical mixture designated in §§ 1310.12 and 1310.13 that the Administrator has exempted from regulation.

* * * * *

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.04 is proposed to be amended by adding a new paragraph (h) as follows:

§ 1310.04 Maintenance of records.

* * * * *

(h) The thresholds and conditions in 21 CFR 1310.04(f) and 1310.04(g) will apply to transactions involving regulated chemical mixtures. All regulated chemical mixtures containing List I and List II chemicals with the exception of acetone, ethyl ether, methyl ethyl ketone, toluene and methyl isobutyl ketone will have the threshold determined by taking the weight of the listed chemical in the regulated mixture. Regulated chemical mixtures that contain one or more of the List II chemicals acetone, ethyl ether, methyl ethyl ketone, toluene and methyl isobutyl ketone will have the threshold determined by taking the entire weight of the mixture. The threshold for these mixtures will be 1500 kilograms for export to the western hemisphere except Canada and 150 kiograms for domestic transactions.

3. Part 1310 is proposed to be amended by adding new sections 1310.12 and 1310.13 as follows:

§ 1310.12 Exempt chemical mixtures.

(a) The chemical mixtures meeting the criteria in paragraphs (c), (d) and (g) of this section are exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to § 1310.12 or § 1310.13 affects the criminal liability of illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture.

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the 'Table of Concentration Limits' are designated as exempt chemical mixtures for the purpose set forth in this section. Calculation of percent by weight or by volume is given in the Table along with the concentration limit and other relative information.

TABLE OF CONCENTRATION LIMITS

List I chemicals	The DEA chemical code no.	Concentration (percent)	Special conditions
N-Acetylanthranilic acid, its salts and esters.	8522	20% by weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Anthranilic acid, and its salts and esters	8530	20% by weight	Concentration based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	30% by volume.	
Benzyl cyanide	8570	20% by volume.	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	2% by weight	Concentration based on any combination of ephedrine, pseudoephedrine, and their salts, optical isomers and salts of optical isomers.
Ergonovine and its salts	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.
Ergotamine and its salts	8676	Not exempt at any concentration.	Chemical mixtures containing any amount of ergotamine, including its salts, are not exempt.
Ethylamine and its salts	8678	20% by weight	Ethylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on ethylamine in the mixture and not the combined weight of carrier solvent, if any.
Hydriodic acid	6695	20% by weight	Aqueous or alcoholic solutions are not considered mixtures.
Isosafrole	8704	20% by volume ...	Concentration in mixture cannot exceed 20% if taken alone or in any combination with safrole.
Methylamine, and its salts	8520	20% by weight	Methylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on methylamine in the mixture and not the combined weight of carrier solvent, if any.
3,4-Methylenedioxyphenyl-2-propanone	8502	20% by weight.	
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by weight ...	Concentration based on any combination of N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers.
N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8119	0.1% by weight ...	Concentration based on any combination of N-methylpseudoephedrine N-methylephedrine, and their salts, optical isomers and salts of optical isomers.
Nitroethane	6724	20% by volume.	
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by weight ...	Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
Phenylacetic acid, and its salts and esters.	8791	20% by weight	Concentration based on any combination of phenylacetic acid and its salts and esters.
Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by weight ...	Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers.
Piperidine, and its salts	2704	20% by volume ...	Concentration based on any combination of piperidine and its salts.
Piperonal	8750	20% by weight.	
Propionic anhydride	8328	20% by volume.	
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	2% by weight	Concentration based on any combination of pseudoephedrine, ephedrine, and their salts, optical isomers and salts of optical isomers.
Safrole	8323	20% by volume ...	Concentration in mixture cannot exceed 20% if taken alone or in any combination with isosafrole.

List II chemicals	The DEA chemical code no.	Concentration (percent)	Special conditions
Acetic Anhydride	8519	20% by volume.	
Acetone	6532	35% by volume ...	Limit applies to acetone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.
Benzyl chloride	8568	20% by volume.	
Ethyl ether	6584	35% by volume ...	Limit applies to ethyl ether or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid	6545	20% by weight	Aqueous or alcoholic solutions are not considered mixtures.
Iodine	6699	20% by weight.	
Methyl ethyl ketone	6714	35% by volume ...	Limit applies to methyl ethyl ketone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.

List II chemicals	The DEA chemical code no.	Concentration (percent)	Special conditions
Methyl isobutyl ketone	6715	35% by volume	Limit applies to methyl isobutyl ketone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.
Potassium permanganate	6579	15% by weight.	
Sulfuric acid	6552	20% by weight	Aqueous solutions are not considered mixtures.
Toluene	6594	35% by volume	Limit applies to toluene or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.

(d) The following categories of chemical mixtures are automatically exempt from the provisions of the Controlled Substances Act as described in paragraph (a) of this section:

(1) Chemical mixtures that are distributed directly to an incinerator for destruction and are subject to the United States Environmental Protection Agency documentation on EPA Form 8700–22 and 8700–22A, provided that the person distributing the mixture to the incinerator maintains and makes available to agents of the Administration upon request such documentation for a period of no less than two years.

(2) Completely formulated paints/coatings that meet the American Society for Testing Materials specifications for the product. A completely formulated paint/coating are only those formulations that contain all the components of the paint/coating for use in the final application without the need to add any additional substances except possibly a thinner. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative or functional adherent film after application.

(3) Harvested plant material that is in its natural state or has been processed in a way that preserves the natural constituents in the ratios that are found in the plant's natural state. Plant material subjected to chemical or physical extraction, concentration, chemical reaction or other treatment that alters the plant's natural constituents or the ratios of the plant constituents are not exempt.

(e) The Administrator may at any time terminate or modify the exemption for any chemical mixture which has been granted an exemption pursuant to the concentration limits as specified in § 1310.12(c); or the exemption provisions for specific categories of chemical mixtures as specified in § 1310.12(d), if evidence of diversion or attempted diversion is found. In terminating or modifying an exemption, the Administrator shall issue and publish in the **Federal Register** notification of the removal of an exempt product or group of exempt products for which evidence of diversion has been found. This order shall include a reference to the legal authority under which the order is based and shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the **Federal Register.** If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(f) The Administrator may upon evidence of diversion or attempted diversion modify any part of the criteria for exemption as specified in § 1310.12(c) and § 1310.12(d). In doing so, the Administrator shall issue and publish a Notice of Proposed Rulemaking in the **Federal Register**. The Administrator shall permit any interested persons to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the **Federal Register** a final order.

§ 1310.13 Exemption of chemical mixtures; application.

(a) The Administrator may, by publication of a Final Rule in the **Federal Register**, exempt from the application of all or any part of the Act, a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

(b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537.

(c) An application for exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture and, if the applicant formulates or manufactures the chemical mixture for other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared;

(4) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non listed chemicals) and its intended use;

(5) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals;

(6) A statement which the applicant believes is justification for granting an exemption for the chemical mixture. The statement must explain how the chemical mixture meets the exemption criteria set forth in paragraph (a) of this section.

(7) The application will include a statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture granted exemption

under § 1310.13 if evidence of diversion of the mixture, or similar mixture, is found.

(8) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

(d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator will notify the applicant of acceptance or nonacceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is granted the applicant shall be notified in writing and the Administrator shall issue and publish in the **Federal Register** an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested persons to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

(f) The Administrator may at any time terminate or modify any product or product line granted an exemption pursuant to paragraph (e) of this section. In terminating or modifying an exemption, the Administrator shall issue and publish in the **Federal Register** notification of the removal of an exempt product or group of exempt products for which evidence of diversion has been found. This order shall include a reference to the legal authority under which the order is based and shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the **Federal Register**. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(g) Any change in the quantitative or qualitative composition of a chemical mixture which has been granted an exemption by application will require a new application for exemption unless such change causes the newly formulated mixture to be automatically exempt by definition in § 1310.12. A new application is not necessary for a change in name or other designation, code, or any identifier. For such changes or additions a written notification is required. The DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

(h) Each manufacturer which desires a mixture to be exempt must apply separately as only those products specifically named in this exempted category will be recognized. Companies which have similar products to those in an exempted category must request and receive separate approval for their product line.

(i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as exempt chemical mixtures for the purposes set forth in this section:

EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name	Form	Date
[Reserved] ...	.....	.....	.....

Dated: September 1, 1998.

Donnie R. Marshall,

Acting Deputy Administrator.

[FR Doc. 98–24293 Filed 9–15–98; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 122–4078b; FRL–6160–7]

Approval and Promulgation of Air Quality Implementation Plans; Commonwealth of Pennsylvania; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes approval of the Commonwealth of Pennsylvania's August 21, 1998 submission to supplement its State Implementation Plan (SIP) revision for the enhanced motor vehicle emissions inspection and maintenance (I/M) program. The Commonwealth's August 1998 submission addresses seven minor, de minimus deficiencies. In addition, Pennsylvania submitted a demonstration of the effectiveness of its decentralized network, as required by the National Highway Systems Designation Act of 1995 (NHSDA). Approval of this submission will remove all remaining de minimus conditions imposed by EPA in its January 28, 1997 interim conditional approval of the Commonwealth of Pennsylvania's March 1996 enhanced I/M SIP revision. This action proposes approval of Pennsylvania's decentralized network effectiveness demonstration. Because EPA is proposing approval of that demonstration, as well as all remaining de minimus deficiencies related to Pennsylvania's enhanced I/M SIP, EPA hereby proposes to convert the interim approval of the Commonwealth's I/M SIP, granted under the NHSDA, to full approval. Because Pennsylvania must still provide specific information related to one condition of EPA's January 28, 1998 approval, the Commonwealth's I/M SIP would remain conditionally approved under the Clean Air Act. In the Final Rules section of this **Federal Register**, EPA is issuing a direct final rule approving the Commonwealth's August 21, 1998 submission. The Agency views this rulemaking action as noncontroversial and anticipates no adverse public comment. A detailed rationale for the approval is set forth in the direct final rule and in the technical support document prepared by EPA for this action. If no adverse comments are received, no further activity is contemplated with relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and

all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by October 16, 1998.

ADDRESSES: Written comments should be addressed to Marcia Spink, Associate Director, Air Programs, Mailcode 3AP20, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street—14th Floor, Philadelphia, Pennsylvania 19103. Copies of relevant documents may also be inspected at the Pennsylvania Department of Environmental Resources Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, by phone at (215) 814–2176, or via e-mail at rehn.brian@epamail.epa.gov, or in writing at the EPA Region III address above.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title, ''Commonwealth of Pennsylvania; Enhanced Motor Vehicle Inspection and Maintenance Program'' which is located in the Rules and Regulations section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 28, 1998.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 98–24732 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50633; FRL–6024–9]

RIN 2070–AB27

Proposed Revocation of Significant New Use Rules for Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke significant new use rules (SNURs) for 6 substances promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for certain chemical substances based on new data. Based on the new data the Agency no longer finds that activities not described in the corresponding TSCA section 5(e) consent order or the premanufacture notice (PMN) for these chemical substances may result in significant changes in human or environmental exposure.

DATES: Written comments must be received by EPA by October 16, 1998.

ADDRESSES: Each comment must bear the docket control number OPPTS–50633 and the name(s) of the chemical substance(s) subject to the comment. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G–099, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically to: oppt.ncic@epa.gov. Follow the instructions under Unit III. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this rulemaking. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–531, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document are available from the EPA Home Page at the **Federal Register**-Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

In the **Federal Register** referenced for each substance, EPA issued a SNUR establishing significant new uses for the substances listed in Unit II. of this preamble, OPPTS–50569A, September 18, l989 (54 FR 38381); OPPTS–50582, August 15, 1990 (55 FR 33296); OPPTS–50613, October 4, 1993 (58 FR 51694); OPPTS–50623, December 2, 1996 (61 FR 63726) (FRL–4964–3); and OPPTS–50628, January 22, l998 (63 FR 3393) (FRL–5720–3). Because of additional data EPA has received for these substances, EPA is hereby proposing to revoke the SNURs.

I. Rationale for Revocation of the Proposed Rule

During EPA's review of the PMNs submitted under section 5(a)(1)(A) of TSCA for the chemical substances subject to this revocation, EPA concluded that promulgation of SNURs under section 5(a)(2) of TSCA was warranted based on the fact that activities not described in the TSCA section 5(e) consent orders or the PMN might result in significant changes in human or environmental exposure. Based on these findings, SNURs were promulgated defining such activities as ''significant new uses''.

Based on new data, EPA has revoked, or will revoke the TSCA section 5(e) consent orders that are the basis for these SNURs and no longer finds that activities not described in the TSCA section 5(e) consent orders or the PMN may result in significant changes in human or environmental exposure nor constitutes ''significant new uses''. The proposed revocation of SNURs for these substances is consistent with this finding. When this revocation becomes final, notice of intent to manufacture, import, or process these substances for a significant new use will no longer be required. In addition, export notification under section 12(b) of TSCA will no longer be required on the basis of these substances being subject to SNURs.

II. Proposed Revocations and Background

EPA is proposing to revoke the significant new use and recordkeeping requirements under 40 CFR part 721, subpart E for several chemical substances. In this unit, EPA provides a description for each substance, including its premanufacture notice (PMN) number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if assigned), the date of the revocation of the section 5(e) consent order (where applicable), a

summary of the reason for revoking the rule, **Federal Register** reference, docket number, and the CFR citation removed in the regulatory text section of this proposed rule. Further background information for the substances is contained in the rulemaking record referenced below in Unit III. of this preamble.

PMN Number P–88–1617

Chemical name: (generic) Terpenes and terpenoids, limonene fraction, polymer with substituted carbopolycycles.
CAS number: Not available.
Federal Register *publication date and reference:* August 15, 1990 (55 FR 33296).
Docket number: OPPTS–50582.
Basis for revocation: Based on the Agency's analysis of potential exposures and the test data submitted pursuant to the TSCA section 5(e) consent order, EPA no longer finds that activities described as ''significant new uses'' in the SNUR may result in significant changes in human exposure. Accordingly, EPA has determined that further regulation under TSCA section 5(a)(2) is not warranted at this time.
Toxicity results: An oral 28-day repeated dose neurotoxicity study in rats: A no observed adverse effect level (NOAEL) of 10 milligrams/kilograms/day (mg/kg/day) was established for female rats based on a dose related depression in body weight gain at 100 mg/kg/day and 1000 mg/kg/day. A NOAEL of 1000 mg/kg/day was established for male rats based on no effects observed at this dose level which was the highest dose tested.
CFR citation: 40 CFR 721.7360 (Formerly 40 CFR 721.2075).

PMN Number P–86–1322

Chemical name: Mixture of: 1,3-benzenediamine, 2-methyl-4,6-bis (methylthio)- and 1,3-benzenediamine, 4-methyl-2,6-bis (methylthio)-.
CAS number: 104983–85–9 and 102093–68–5.
Revocation of section 5(e) consent order: May 21, 1998.
Federal Register *publication date and reference:* September 18, 1989 (54 FR 38381).
Docket number: OPPTS–50569A.
Basis for revocation: Based on the Agency's analysis of potential exposures and the test data submitted pursuant to the TSCA section 5(e) consent order, EPA no longer finds that activities described as ''significant new uses'' in the SNUR may result in significant changes in human exposure. Accordingly, EPA has determined that further regulation under TSCA section 5(a)(2) is not warranted at this time.
Toxicity results: A 2-year chronic/carcinogenicity study was found to be negative at the doses tested. A NOAEL was established at 100 parts per million (ppm) (4.7 mg/kg/day) in males and 200 ppm (11.9 mg/kg/day) which were the highest doses tested.
CFR citation: 40 CFR 721.1525 (Formerly 40 CFR 721.557).

PMN Numbers P–91–1190 and P–91–1191

Chemical name: (generic) Substituted dichlorobenzothiazoles.
CAS number: Not available.
Federal Register *publication date and reference:* October 4, l993 (58 FR 51694).
Docket number: OPPTS–50613.
Basis for revocation: Based on the Agency's analysis of potential exposures and the data submitted pursuant to the significant new use notice, EPA no longer finds that activities described as ''significant new uses'' in the SNUR may result in significant changes in human exposure. Accordingly, EPA has determined that further regulation is not warranted at this time.
CFR citation: 40 CFR 721.1740.

PMN Number P–94–2159

Chemical name: (generic) Anthraquinone dye.
CAS number: Not available.
Federal Register *publication date and reference:* January 22, 1998 (63 FR 3393).
Docket number: OPPTS–50628.
Basis for revocation: Pursuant to 40 CFR 720.75(e), the submitter withdrew the PMN. Therefore, a new PMN is required before anyone may commence manufacture or import. Since the PMN requirement is applicable to the substance, a SNUR is unwarranted at this time and EPA is revoking the SNUR.
CFR citation: 40 CFR 721.723.

PMN Number P–94–2061

Chemical name: (generic) Benzotriazole derivative.
CAS number: Not available.
Revocation of section 5(e) consent order: March 17, 1998.
Federal Register *publication date and reference:* December 2, 1996 (61 FR 63726).
Docket number: OPPTS–50623.
Basis for revocation: Based on the Agency's analysis of potential exposures and the test data submitted pursuant to the consent order, EPA no longer finds that activities described as ''significant new uses'' in the SNUR may result in significant changes in human exposure. Accordingly, EPA has determined that further regulation under TSCA section 5(a)(2) is not warranted at this time.
Toxicity results: The 90-day oral study in rats demonstrated a NOAEL of 1000 mg/kg/day. Inhalation exposures during manufacturing and processing to workers may approach 214 mg/kg/day. The margin of exposure (MOE) for workers is 467 during manufacturing/processing and 5,882 for use. The MOEs are adequate given the estimates for inhalation.
CFR citation: 40 CFR 721.1737.

III. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPPTS–50633 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located in the TSCA Nonconfidential Information Center Rm. NE–B607, 401 M St., SW., Washington, DC.

Electronic comments can be sent directly to EPA at:
oppt.ncic@epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPPTS–50633. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

IV. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This proposed rule revokes or eliminates an existing regulatory requirement and does not contain any new or amended requirements. As such, the Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Since this proposed rule does not impose any requirements, it does not contain any information collections subject to approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or require any other action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require special considerations as required by

Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency has determined that SNUR revocations, which eliminate requirements without imposing any new ones, have no adverse economic impacts. The Agency's generic certification for SNUR revocations appears on June 2, 1997 (62 FR 29684) (FRL–5597–1) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing Intergovernmental Partnerships* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the OMB a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's proposed rule does not create an unfunded federal mandate on State, local or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the proposed rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposed rule.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 9, 1998.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

§§ 721.723, 721.1525, 721.1737, 721.1740, 721.7360 [Removed]

2. By removing § § 721.723, 721.1525, 721.1737, 721.1740, and 721.7360.

[FR Doc. 98–24843 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 61, 63, and 69

[CC Docket No. 98–131; FCC 98–164]

1998 Biennial Regulatory Review

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Section 11 of the Communications Act of 1934, as amended (Act), requires that the Commission, in every even-numbered year beginning in 1998, review all regulations that apply to the operations and activities of any provider of telecommunications service and determine whether any of these regulations are no longer necessary in the public interest as the result of meaningful economic competition between providers of the service. As part of this 1998 biennial regulatory review, the Commission proposes to revise part 61 to, among other things, eliminate requirements that eliminate several rules that no longer seem to serve any useful purpose, and to reorganize part 61 to clarify which rules apply to which carriers.

DATES: Comments are due on or before October 16, 1998. Reply comments are due on or before November 16, 1998.

Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998. Comments filed through the ECFS can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html>. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should include the following words in the body of the message, ''get form <your e-mail address.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or

rulemaking number appear in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 1919 M St. N.W., Room 222, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Steven Spaeth, Competitive Pricing Division, Common Carrier Bureau, (202) 418–1530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking adopted July 15, 1998. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Public Reference Room (Room 230), 1919 M Street, N.W., Washington, D.C. 20554. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Suite 140, 2100 M Street, N.W., Washington, D.C. 20037.

Regulatory Flexibility Analysis

Pursuant to section 603 of the Regulatory Flexibility Act, the Commission has prepared the following initial regulatory flexibility analysis (IRFA) of the expected impact of these proposed policies and rules on small entities. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the regulatory flexibility analysis. The Office of Public Affairs, Reference Operation Division, shall cause a copy of the Notice, including the initial regulatory flexibility analysis, to be sent to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981).

Reason for action. The Telecommunications Act of 1996 requires the Commission in every even-numbered year beginning in 1998 to review all regulations that apply to the operations or activities of any provider of telecommunications service and to determine whether any such regulation is no longer necessary in the public interest due to meaningful economic competition.

Objectives. To repeal or modify any rules in part 61 that are no longer necessary in the public interest, as required by section 11 of the Communications Act of 1934, as amended.

Legal Basis. The proposed action is supported by section 11 of the Communications Act of 1934, as amended, 47 U.S.C. 161.

Description, potential impact and number of small entities affected. For purposes of this Notice, the Regulatory Flexibility Act defines a ''small business'' to be the same as a ''small business concern'' under the Small Business Act (SBA), 15 U.S.C. 632, unless the Commission has developed one or more definitions that are appropriate to its activities. *See* 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). Under the SBA, a ''small business concern'' is one that: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the SBA. 15 U.S.C. 632. The Small Business Administration has defined a small business for Standard Industrial Classification (SIC) category 4813 (Telephone Communications, Except Radiotelephone) to be small entities when they have fewer than 1500 employees. 13 CFR 121.201.

Total number of telephone companies affected. The proposals under consideration in this Notice, if adopted, would affect all telecommunications carriers regulated by the Commission. The United States Bureau of the Census (Census Bureau) reports that, at the end of 1992, there were 3497 firms engaged in providing telephone service, as defined therein, for at least one year. United States Department of Commerce, Bureau of the Census, *1992 Census of Transportation, Communications, and Utilities, Establishment and Firm Size,* at Firm Size 1–123 (1995). This number contains a variety of different categories of carriers, including LECs, interexchange carriers, competitive access providers, cellular carriers, mobile service carriers, operator service providers, pay telephone operators, PCS providers, covered SMR providers, and resellers. It seems certain that some of those 3497 telephone service firms may not qualify as small entities or small incumbent LECs because they are not independently owned or operated. 15 U.S.C. 632(a)(1).

We believe that dominant carriers are not small businesses for IRFA purposes because they are dominant in their field of operation. We have found incumbent LECs to be ''dominant in their field of operation'' since the early 1980s, and we consistently have certified under the Regulatory Flexibility Act, 5 USC 605(b), that incumbent LECs are not subject to regulatory flexibility analysis requirements because they are not small businesses. *See, e.g.*, Expanded Interconnection with Local Telephone Companies, Supplemental Notice of Proposed Rulemaking, 6 FCC Rcd 5809 (1991); MTS and WATS Market Structure, Report and Order, 2 FCC Rcd 2953, 2959 (1987) (citing MTS and WATS Market Structure, Third Report and Order, 93 FCC 2d 241, 338–39 (1983)). In order to remove any possible issue of Regulatory Flexibility Act compliance, we nevertheless tentatively conclude that dominant carriers should be included in this IRFA. We seek comment on this tentative conclusion.

Reporting, record keeping and other compliance requirements. None of the proposed rules in this notice are intended to increase the reporting, record keeping and other compliance requirements of any telecommunications carrier.

Federal rules which overlap, duplicate or conflict with this rule. None.

Any significant alternatives minimizing impact on small entities and consistent with stated objectives. As explained above, it is not clear at this stage of the proceeding whether any of the parties that will be affected by these proposed rules, if adopted, can be considered ''small entities'' within the meaning of section 603(c). At this time, we have not eliminated any alternatives from our consideration.

Summary of Report and Order

In this Notice of Proposed Rulemaking, we seek comment on the proposed rules listed below. In particular, we seek comment on the following: (1) codifying rules to be applicable to carriers submitting tariff filing fees electronically; (2) revising section 61.72, requiring issuing carriers to post their tariffs, *i.e.*, keep them accessible to the public during normal business hours; (3) reducing the minimum effective period for nondominant carriers' tariffs, from 30 days to 15 days; (4) separating our part 61 rules into subparts so carriers can determine more easily which rules apply to them; (5) clarifying the notice requirement rules; (6) eliminating an apparently inaccurate definition in the nondominant carrier tariff rules; (7) requiring carriers to maintain separate tariffs for domestic and international services; and (8) updating the Commission's price cap rules and eliminating those that are no longer applicable to any carrier, such as the interexchange carrier price cap rules.

Ordering Clause

Accordingly, pursuant to section 11 of the Communications Act of 1934, as amended, 47 U.S.C. 161, *it is ordered that notice is hereby given of* the rulemaking as described and that *comment is sought* on these issues.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

List of Subjects

47 CFR Part 61

Communications common carriers, Tariffs.

47 CFR Parts 63 and 69

Communications common carriers, Tariffs.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 61, 63, and 69 of the Code of Federal Regulations as follows:

The authority citation continues to read as follows:

Authority: Secs. 1, 4(i), 4(j), 201–205, and 403 of the Communications Act of 1934, as amended; 47 U.S.C. 151, 154(i), 154(j), 201–205, and 403, unless otherwise noted.

§§ 61.1 through 61.3 [Amended]

2. Designate §§ 61.1 through 61.3 as subpart A and add a subpart heading entitled ''Subpart A—General'' immediately preceding § 61.1.

3. Revise § 61.2 to read as follows:

§ 61.2 General tariff requirements.

(a) In order to remove all doubt as to their proper application, all tariff publications must contain clear and explicit explanatory statements regarding the rates and regulations.

(b) Tariff publications must be delivered to the Commission free from all charges, including claims of postage.

(c) Tariff publications will not be returned.

4. Remove the undesignated center heading ''Definitions'' immediately preceding § 61.3.

5. Amend § 61.3 by revising paragraphs (e), (w), and (y), to read as follows:

§ 61.3 Definitions.

* * * * *

(e) *Base period.* For carriers subject to §§ 61.41–61.49, the 12-month period ending six months prior to the effective date of annual price cap tariffs. Base year or base period earnings shall exclude amounts associated with exogenous adjustments to the PCI for the lower formula adjustment mechanism permitted by § 61.45(d)(1)(vii).

* * * * *

(w) *Price Cap Index (PCI).* An index of prices applying to each basket of services of each carrier subject to price cap regulation, and calculated pursuant to § 61.45.

* * * * *

(y) *Price cap tariff.* Any tariff filing involving a service subject to price cap regulation, or that requires calculations pursuant to §§ 61.45, 61.46, or 61.47.

* * * * *

6. Remove the undesignated center headings ''GENERAL RULES'' and ''Rules for Electronic Filing'' immediately preceding § 61.13.

§§ 61.13 through 61.17 [Amended]

7. Designate §§ 61.13 through 61.17 as subpart B and add a subpart heading entitled ''Subpart B—Rules for Electronic Filing'' immediately preceding § 61.13.

8. Remove the undesignated center heading ''General Rules for Domestic and International Nondominant Carriers'' immediately preceding § 61.20.

§§ 61.20–61.24 [Amended]

9. Designate §§ 61.20 through 61.24 as subpart C and add a subpart heading entitled ''Subpart C—General Rules for Nondominant Carriers'' immediately preceding § 61.20.

10. Add § 61.18 to subpart C to read as follows:

§ 61.18 Scope.

The rules in this subpart apply to all nondominant carriers.

§§ 61.20 through 61.24 [Redesignated as §§ 61.19 through 61.23]

11. Redesignate §§ 61.20 through 61.24 as §§ 61.19 through 61.23.

12. In newly redesignated § 61.19, revise paragraphs (b) and (c) to read as follows:

§ 61.19 Detariffing of domestic, interstate, interexchange services.

* * * * *

(b) Carriers that are nondominant in the provision of domestic, interstate, interexchange services are permitted to file tariffs for dial-around 1+services. For the purposes of this paragraph, dial-around 1+calls are those calls made by accessing the interexchange carrier through the use of that carrier's carrier access code.

(c) Carriers that are nondominant in the provision of domestic, interstate, interexchange services are permitted to file a tariff for such interstate service applicable to those customers who contact the local exchange carrier to designate an interexchange carrier or to initiate a change with respect to their primary interexchange carrier. Such tariff will enable the interexchange carrier to provide service to the customer until the interexchange carrier and the customer consummate a written agreement, but in no event shall the interexchange carrier provide service to its customer pursuant to such tariff for more than 45 days.

13. In newly redesignated § 61.20, revise paragraphs (b)(1) and (c) to read as follows:

§ 61.20 Method of filing publications.

* * * * *

(b)(1) In addition, except for issuing carriers filing tariffing fees electronically, for all tariff publications requiring fees as set forth in part 1, subpart G of this chapter, issuing carriers must submit the original of the cover letter (without attachments), FCC Form 159, and the appropriate fee to the Mellon Bank, Pittsburgh, PA at the address set forth in § 1.1105 of this chapter. Issuing carriers submitting tariff fees electronically should submit the Form 159 and the original cover letter to the Secretary of the Commission in lieu of the Mellon Bank. The Form 159 should display the Electronic Audit Code in the box in the upper left hand corner marked ''reserved.'' Issuing carriers should submit these fee materials on the same date as the submission in paragraph (a) of this section.

* * * * *

(c) In addition to the requirements set forth in paragraphs (a) and (b) of this section, the issuing carrier must send a copy of the cover letter with one 3½ inch diskette or CD–ROM containing both the complete tariff and any attachments, as appropriate, to the Secretary, Federal Communications Commission. In addition, the issuing carrier must send one diskette or CD–ROM of the complete tariff and a copy of the cover letter to the commercial contractor (at its office on Commission premises), and to the Chief, Tariff and Pricing Analysis Branch. The latter should be clearly labeled as the ''Public Reference Copy.'' The issuing carrier should file the copies required by this paragraph so they will be received on the same date as the filings in paragraph (a) of this section. In cases where the a single diskette or CD–ROM does not provide sufficient capacity for the carrier's entire tariff filing, the issuing carrier may submit two or more diskettes, or two or more CD–ROMs, as necessary.

14. In newly redesignated § 61.21, revise paragraph (a)(1) to read as follows:

§ 61.21 Cover letters.

(a)(1) Except as specified in § 61.32(b), all publications filed with the Commission must be accompanied by a cover letter, 8.5 by 11 inches (21.6 cm × 27.9 cm) in size, and must be plainly printed in black ink. All transmittal letters should briefly explain the nature and purpose of the filing and indicate the date and method of filing of the original cover letter, as required by § 61.20(b)(1) of this part.

* * * * *

15. Immediately after newly redesignated § 61.21, remove the undesignated center heading ''Specific Rules For Domestic and International Nondominant Carriers''.

16. In newly redesignated § 61.22, revise paragraph (a), redesignate paragraph (c) as paragraph (c)(1), and add paragraphs (c)(2) and (e) to read as follows:

§ 61.22 Composition of tariffs.

(a) The tariff must be submitted on a 3½ inch (8.89 cm) diskette, or a 5 inch CD–ROM, formatted in an IBM-compatible form using either WordPerfect 5.1 or Microsoft Word 6 software. Neither diskettes nor CD–ROMs shall contain more than one tariff. The diskette or CD–ROM must be submitted in ''read only'' mode. The diskette or CD–ROM must be clearly labelled with the carrier's name, Tariff Number, software used, and the date of submission. When multiple diskettes or CD–ROMs are submitted, the issuing carrier shall clearly label each diskette in the following format: ''1 of ____'', ''2 of ____'', etc.

* * * * *

(c) * * *

(2) Any issuing carrier submitting tariffs on ten or more diskettes that wishes to revise its tariff is permitted to do so by refiling only those diskettes on which the changed material is located. Any such carrier shall file a current effective version of their entire tariff on the first business day of each month. For purposes of this paragraph, ''business day'' is defined in § 1.4(e)(2) of this chapter.

* * * * *

(e) For contract-based tariffs defined in § 61.3(m), a separate letter of transmittal must accompany each tariff filed. The transmittals must be numbered in a series separate from transmittals for non-contract tariff filing. Numbers must appear on the face of the transmittal and be in the form of ''CTT No. ____'', using CTT as an abbreviation for contract-based tariff transmittals. Contract-based tariffs must also be numbered in a series separate from non-contract-based tariffs. Numbers must be in the form of ''CT No. ____'', using CT as an abbreviation for contract-based tariffs. Each contract-based tariff must be assigned a separate number. Transmittals and tariffs subject to this paragraph shall be filed beginning with the number ''1'' and shall be numbered consecutively.

17. In newly redesignated § 61.23, revise paragraph (c) to read as follows:

§ 61.23 Notice requirements.

* * * * *

(c) All tariff filings of domestic and international non-dominant carriers must be made on at least one day's notice.

18. Add new § 61.24 to subpart C to read as follows:

§ 61.24 Effective period required before changes.

(a) Except as provided in § 61.23(c)(3) or except as otherwise provided by the Commission, new rates or regulations must be in effect for at least 15 days before a nondominant carrier will be permitted to make any change.

(b) Changes to rates and regulations that have not yet become effective, *i.e.*, are pending, may not be made unless the effective date of the proposed changes is at least 15 days after the scheduled effective date of the pending revisions.

19. Add § 61.25 to subpart C to read as follows:

§ 61.25 References to other instruments.

A non-dominant carrier may cross-reference in its tariff publication only the rate provisions of another carrier's FCC tariff publication, provided that the following conditions are met:

(a) The tariff being cross-referenced must be on file with the Commission and in effect;

(b) The issuing carrier must specifically identify in its tariff the cross-referenced tariff by Carrier Name and FCC Tariff Number;

(c) The issuing carrier must specifically identify in its tariff the rates being cross-referenced so as to leave no doubt as to the exact rates that will apply, including but not limited to any applicable credits, discounts, promotions; and

(d) The issuing carrier must keep its cross-references current.

20. Add a subpart D to part 61, consisting of § 61.28, to read as follows:

Subpart D—General Tariff Rules for International Dominant Carriers

§ 61.28 International dominant carrier tariff filing requirements.

(a) Any carrier classified as dominant for the provision of particular international communications services on a particular route due only to a foreign carrier affiliation pursuant to § 63.10 shall file tariffs for those services on at least one day's notice without cost support.

(b) Any carrier classified as dominant for the provision of particular international communications services on a particular route for any reason other than a foreign carrier affiliation pursuant to § 63.10 shall file tariffs for those services pursuant to the notice and cost support requirements for tariff filings of dominant domestic carriers, as set forth in subpart E of this part.

(c) For all tariff filing requirements other than notice and cost support requirements, any carrier classified as dominant for the provision of particular international communications services on a particular route shall file tariffs for those services pursuant to the general rules for nondominant carriers set forth in subpart C of this part.

21. Designate §§ 61.32 through 61.52, 61.54, 61.58, and 61.59 as subpart E and add a subpart heading entitled ''Subpart E—General Rules for Dominant Carriers'' immediately preceding § 61.32.

22. Add § 61.31 to subpart E to read as follows:

§ 61.31 Scope.

The rules in this subpart apply to all dominant carriers.

23. Amend § 61.32 by revising paragraph (b) to read as follows:

§ 61.32 Method of filing publications.

* * * * *

(b) In addition, except for issuing carriers filing tariffing fees electronically, for all tariff publications requiring fees as set forth in part 1, subpart G of this chapter, issuing carriers must submit the original of the transmittal letter (without attachments), FCC Form 159, and the appropriate fee to the Mellon Bank, Pittsburgh, PA, at the address set forth in § 1.1105 of this chapter. Issuing carriers submitting tariff fees electronically should submit the Form 159 and the original cover letter to the Secretary of the Commission in lieu of the Mellon Bank. The Form 159 should display the Electronic Audit Code in the box in the upper left hand corner marked ''reserved.'' Issuing carriers should

submit these fee materials on the same date as the submission in paragraph (a).

* * * * *

24. In § 61.33, revise the first sentence of the introductory text of paragraph (a) and the first sentence of § 61.33(h)(2) to read as follows:

§ 61.33 Letters of transmittal.

(a) Except as specified in § 61.32(b), all publications filed with the Commission must be numbered consecutively by the issuing carrier beginning with Number 1, and must be accompanied by a letter of transmittal, (21 cm × 29.7 cm) or 8½ by 11 inches (21.6 cm × 27.9 cm) in size. * * *

* * * * *

(h) * * *

(2) For contract-based tariffs defined in § 61.3(m), a separate letter of transmittal may accompany each tariff filed, or the above format may be modified for filing as many publications as may be desired with one transmittal letter. * * *

§ 61.35 [Removed]

25. Remove § 61.35.

§ 61.36 [Removed]

26. Remove § 61.36.

27. Amend § 61.38 by revising paragraph (a), removing and reserving paragraph (b)(3), and adding paragraph (g) to read as follows:

§ 61.38 Supporting information to be submitted with letters of transmittal.

(a) *Scope.* This section applies to dominant carriers whose gross annual revenues exceed $500,000 for the most recent 12 month period of operations or are estimated to exceed $500,000 for a representative 12 month period. Local exchange carriers serving 50,000 or fewer access lines in a given study area that are described as subset 3 carriers in § 69.602 of this chapter may submit Access Tariff filings for that study area pursuant to either this section or § 61.39. However, the Commission may require any carrier to submit such information as may be necessary for a review of a tariff filing. This section (other than the preceding sentence of this paragraph) shall not apply to tariff filings proposing rates for services identified in § 61.42(d), (e), and (g).

* * * * *

(g) Above the bottom margin of each page of cost support material submitted pursuant to this section, the carrier shall indicate the transmittal number under which that page was submitted.

28. Amend § 61.39 by revising paragraph (a) and by adding paragraph (f) to read as follows:

§ 61.39 Optional supporting information to be submitted with letters of transmittal for Access Tariff filings effective on or after April 1, 1989, by local exchange carriers serving 50,000 or fewer access lines in a given study area that are described as subset 3 carriers in § 69.602.

(a) *Scope.* This section provides for an optional method of filing for any local exchange carrier that is described as subset 3 carrier in § 69.602, which elects to issue its own Access Tariff for a period commencing on or after April 1, 1989, and which serves 50,000 or fewer access lines in a study area as determined under § 36.611(a)(8) of this chapter. However, the Commission may require any carrier to submit such information as may be necessary for review of a tariff filing. This section (other than the preceding sentence of this paragraph) shall not apply to tariff filings of local exchange carriers subject to price cap regulation.

* * * * *

(f) Above the bottom margin of each page of cost support material submitted pursuant to this section, the carrier shall indicate the transmittal number under which that page was submitted.

§ 61.41 [Amended]

29. In § 61.41, remove and reserve paragraph (a)(1).

30. Amend § 61.42 by removing and reserving paragraphs (a), (b) and (c), by adding a sentence at the end of paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(6), and by revising the first sentence of paragraph (g) to read as follows:

§ 61.42 Price cap baskets and service categories.

(a) [Reserved]

(b) [Reserved]

(c) [Reserved]

(d) * * *

(1) * * * For purposes of §§ 61.41 through 61.49 of this chapter, this basket shall be referred to as the ''common line basket.''

(2) * * * For purposes of §§ 61.41 through 61.49, this basket shall be referred to as the ''traffic-sensitive basket.''

(3) * * * For purposes of §§ 61.41 through 61.49, this basket shall be referred to as the ''trunking basket.''

(4) * * * For purposes of §§ 61.41 through 61.49, this basket shall be referred to as the ''interexchange basket.''

(6) * * * For purposes of §§ 61.41 through 61.49, this basket shall be referred to as the ''marketing expense basket.''

* * * * *

(g) New services, other than those within the scope of paragraph (f) of this section, must be included in the affected basket at the first annual price cap tariff filing following completion of the base period in which they are introduced.

* * *

31. Revise § 61.43 to read as follows:

§ 61.43 Annual price cap filings required.

Carriers subject to price cap regulation shall submit annual price cap tariff filings that propose rates for the upcoming year, that make appropriate adjustments to their PCI, API, and SBI values pursuant to §§ 61.45 through 61.47, and that incorporate the costs and rates of new services into the PCI, API, or SBI calculations pursuant to §§ 61.45(g), 61.46(b), and 61.47 (b) and (c). Carriers may propose rate or other tariff changes more often than annually, consistent with the requirements of § 61.59.

§ 61.44 [Reserved]

32. Remove and reserve § 61.44.

33. § 61.45 is amended as follows:

a. Revise paragraph (b);

b. Revise the introductory text and the definition of ''R'' in the formula in paragraph (c)(1);

c. Revise paragraph (c)(2);

d. Add new paragraph (c)(3);

e. Add a new sentence to the end of paragraph (d)(4);

f. In paragraph (f), remove the words ''paragraph (c)'' and add, in their place, the words ''paragraphs (b) and (c)''; and

g. Revise paragraphs (i) and (j)(2).

§ 61.45 Adjustments to the PCI for local exchange carriers.

* * * * *

(b)(1) Adjustments to local exchange carrier PCIs for the traffic-sensitive basket described in § 61.42(d)(2) shall be made pursuant to the following formula:

$PCI_t = PCI_{t-1}[1 + w(GDP - PI - X) + \Delta Z/R]$

Where

GD–PI=the percentage change in the GDP–PI between the quarter ending six months prior to the effective date of the new annual tariff and the corresponding quarter of the previous year,

X=6.5%,

ΔZ = the dollar effect of current regulatory changes when compared to the regulations in effect at the time the PCI was updated to PCI_{t-1}, measured at base period level of operations,

R=an amount calculated by multiplying base period quantities for each rate element in the basket by the price for that rate element at the time the PCI was updated to PCI_{t-1}, summing the results, and adding the products of base period quantities for each PICC established in § 69.153 of this

Chapter and the portion of that PICC that is associated with the basket,

w=R—(access rate in effect at the time the PCI was updated to PCI_{t-1}, multiplied by base period demand)+ΔZ, all divided by R,

PCI_t=the new PCI value, and

PCI_{t-1}=the immediately preceding PCI value.

(2) The ''w(GDP–PI–X)'' component of the PCI formula specified in paragraph (b)(1) of this section shall be employed only in the adjustment made in connection with the annual price cap filing. In calculating the ''w'' variable in the formula detailed in paragraph (b)(1) of this section, the access costs that must be subtracted from the ''R'' variable shall be apportioned among the baskets specified in §§ 61.42(d)(2), (3), (4), and (6) as follows:

(i) The net change in total non-traffic sensitive access costs for all capped services (in all baskets), calculated at base period demand, shall be allocated among the baskets in proportion to each basket's share of total base period non-traffic sensitive minutes of access (both originating and terminating);

(ii) The net change in total traffic sensitive access costs for all capped services (in all baskets), calculated at base period demand, shall be allocated among the baskets in proportion to each basket's share of total base period traffic sensitive minutes of access;

(iii) Changes in special access costs, calculated at base period demand, shall be assigned directly to the trunking basket specified in § 61.42(d)(3).

(3) Adjustments to local exchange carrier PCIs for the trunking basket designated in § 61.42(d)(3) shall be made pursuant to the formula set forth in paragraphs (b)(1) and (2) of this section.

(4) Adjustments to local exchange carrier PCIs for the interexchange basket designated in § 61.42(d)(4) shall be made pursuant to the formula set forth in paragraphs (b)(1) and (2) of this section. Notwithstanding that formula, the value of X for this basket shall be 3.0 percent.

(5) [Reserved]

(6) Adjustments to local exchange carrier PCIs for the marketing expense basket designated in § 61.42(d)(6) shall be made pursuant to the formula set forth in paragraphs (b)(1) and (2) of this section.

(c)(1) In the event that local exchange carrier imposes a per-minute carrier common line charge pursuant to § 69.154 of this chapter, and subject to paragraphs (c)(2) and (c)(3) of this section, adjustments to local exchange carrier PCIs for the common line basket designated in § 61.42(d)(1) shall be made pursuant to the following formula:

* * * * *

R=an amount calculated by multiplying base period quantities for each rate element in the basket by the price for that rate element at the time the PCI was updated to PCI_{t-1}, summing the results, and adding the products of base period quantities for each PICC established in § 69.153 of this Chapter and the portion of that PICC that is associated with the common line basket,

* * * * *

(2) The ''w[(GDP–PI–X–(g/2))/(1+(g/2))]'' component of the PCI formula contained in paragraph (c)(1) of this section shall be employed only in the adjustment made in connection with the annual price cap filing.

(3) The formula set forth in paragraph (c)(1) of this section shall be used by a local exchange carrier only if that carrier is imposing a carrier common line charge pursuant to § 69.154 of this chapter. Otherwise, adjustments to local exchange carrier PCIs for the common line basket designated in § 61.42(d)(1) shall be made pursuant to the formula set forth in § 61.45(b).

(d) * * *

(4) * * * For purposes of this Chapter, exogenous cost changes that are not targeted to a specific price cap service category or subcategory pursuant to Commission Rule or Order shall be referred to as ''untargeted exogenous cost changes.''

* * * * *

(i)(1) Notwithstanding the provisions of paragraphs (b) and (c) of this section, and subject to the limitations of paragraph (j) of this section, any price cap local exchange carrier that charges a per-minute interconnection charge pursuant to § 69.124 or § 69.155 of this chapter during the base year shall not make any reductions to its PCIs associated with its common line and traffic-sensitive baskets in its annual access filing for that year. The PCI reductions for the common line and traffic sensitive baskets that otherwise would be required by paragraphs (b) and (c) of this section shall be applied to the trunking basket. These PCI reductions shall be made after the PCI for the trunking basket described in § 61.42(d)(3) using the PCI formula in § 61.45(b).

(2) Notwithstanding the provisions of paragraph (b) of this section, and subject to the limitations of paragraph (j) of this section, any price cap local exchange carrier that charges a per-minute interconnection charge pursuant to § 69.155 of this chapter during the base year shall not make any reductions to its PCI associated with its marketing expense basket in its annual access filing for the tariff year. That carrier shall apply the PCI reductions that otherwise would be required for the marketing expense basket pursuant to paragraph (b) of this section to the trunking basket. This reduction is to be made after any adjustment made pursuant to paragraph (i)(1) of this section.

(3) [Reserved]

(4) Effective January 1, 1998, the reduction in the PCI for the trunking basket designated in § 61.42(d)(3) that results from paragraphs (i)(1) and (i)(2) of this section shall be determined by multiplying the PCI for the trunking basket by one minus the ratio of the dollar effect of the PCI reductions otherwise applicable to the common line, traffic-sensitive, and marketing expense baskets, to the dollar effect of the PCI reduction for the trunking basket.

(j) * * *

(2) exclude the amount of any exogenous adjustments permitted or required for the common line and traffic sensitive baskets, defined in §§ 61.42(d)(1) and (d)(2), from the retargeting adjustment to the PCI for the trunking basket defined in § 61.42(d)(3).

34. Amend § 61.47 to revise paragraph (e), remove and reserve paragraph (f), and to revise paragraphs (i)(1) and (i)(2) to read as follows:

§ 61.47 Adjustments to the SBI; pricing bands.

* * * * *

(e) Pricing bands shall be established each tariff year for each service category and subcategory within a basket. Except as provided in paragraphs (g) and (h) of this section, each band shall limit the pricing flexibility of the service category or subcategory, as reflected in the SBI, to an annual increase of five percent, relative to the percentage change in the PCI for that basket, measured from the levels in effect on the last day of the preceding tariff year. For local exchange carriers subject to price cap regulation as that term is defined in § 61.3(x), there shall be no lower pricing band for any service category or subcategory.

* * * * *

(i)(1) In the event that a price cap local exchange carrier is imposing an interconnection charge on its access customers pursuant to § 69.124 and/or 69.155, and to the extent that §§ 61.45(b) and 61.45(i) require that local exchange carrier to reduce its PCI for its trunking basket, as defined in § 61.42(d)(3), that carrier is required to reduce its SBI for

its interconnection charge service band, as defined in § 61.42(e)(2)(vi), by an amount proportional to its trunking basket PCI reduction. This SBI reduction shall be determined by dividing the sum of the dollar amount of any PCI reduction required by § 61.45(i), by the dollar amount associated with the SBI for the interconnection charge service band, and multiplying the SBI for the interconnection charge service band by one minus the resulting ratio.

(2) Any exogenous cost reduction that is untargeted within the meaning of § 61.45(d)(4) shall be reflected in other service band indices for service categories in the traffic sensitive and trunking baskets as follows:

(i) For all service band indices other than those listed in paragraphs (ii) and (iii) of this paragraph, untargeted exogenous cost adjustments shall be reflected pursuant to the following formula:

$$SBI_{ul} = SBI_{ul_{t-1}} * \left(1 + \frac{T + \frac{Rsvc_{t-1}}{Rbskt_{t-1}} * U_{bskt}}{Rsvc_{t-1}} \right)$$

Where

SBI_{ul}=the new SBI upper limit;

$SBI_{ul(t-1)}$=the immediately preceding SBI upper limit;

T=the targeted exogenous cost adjustment;

$Rsvc_{t-1}$=R for the service category, where R is calculated by multiplying base period quantities for each rate element in the service category by the price for that rate element at the time the PCI was updated to PCI_{t-1}, and summing the results,

$Rbskt_{t-1}$=R for the basket, where R is calculated by multiplying base period quantities for each rate element in the basket by the base period price for that rate element at the time the PCI was updated to PCI_{t-1}, and summing the results,

U_{bskt}=the untargeted exogenous cost reduction to be associated with the basket.

(ii) For the service band subindices for DS1 and DS3 services defined in §§ 61.42(e)(2)(iii) (A) and (B), the 800 data base vertical features subindex required by §§ 61.47(g)(4), and the density pricing zones for voice grade services and tandem-switched transport permitted by §§ 61.47(h)(1) (iii) and (iv), untargeted exogenous cost adjustments shall be reflected pursuant to the following formula:

$$SBI_{ul} = SBI_{ul_{(t-1)}} * \left(1 + \frac{T + \left(\frac{Rsubsvc_{t-1}}{Rbskt_{t-1}} * U_{bskt} \right) + \left(\frac{Rsubsvc_{t-1}}{Rsvc_{t-1}} * U_{svc} \right)}{Rsubsvc_{t-1}} \right)$$

Where

$Rsubsvc_{t-1}$=R for the service subcategory, where R is calculated by multiplying base period quantities for each rate element in the service subcategory by the base period price for that rate element at the time the PCI was updated to PCI_{t-1}, and summing the results, and

U_{svc}=the untargeted exogenous cost reduction to be associated with the service category.

(iii) For the density pricing zones for DS1 and DS3 services permitted by §§ 61.47(h)(1)(i) and (ii), untargeted exogenous cost adjustments shall be reflected pursuant to the following formula:

$$SBI_{ul} = SBI_{ul_{(t-1)}} * \left(1 + \frac{T + \left(\frac{Rsubsvc_{t-1}}{Rbskt_{t-1}} * U_{bskt} \right) + \left(\frac{Rsubsvc_{t-1}}{Rsvc_{t-1}} * U_{svc} \right) + \left(\frac{Rdz_{t-1}}{Rsubsvc_{t-1}} * U_{subsvc} \right)}{Rdz_{t-1}} \right)$$

Where

Rdz_{t-1}=R for the density pricing zone, where R is calculated by multiplying base period quantities for each rate element in the zone by the base period price for that rate element at the time the PCI was updated to PCI_{t-1}, and summing the results, and

U_{subsvc}=the untargeted exogenous cost reduction to be associated with the service subcategory.

* * * * *

§ 61.48 [Amended]

Amend § 61.48 by removing and reserving paragraphs (a) through (h), and to remove and reserve paragraph (i)(3)(ii).

36. Amend § 61.49 to revise paragraph (a), revise paragraph (c), remove and reserve paragraph (f), remove and reserve paragraph (i)(1), and add new paragraph (l) to read as follows:

§ 61.49 Supporting information to be submitted with letters of transmittal for tariffs of carriers subject to price cap regulation.

(a) Each price cap tariff filing must be accompanied by supporting materials

sufficient to calculate required adjustments to each PCI, API, and SBI pursuant to the methodologies provided in §§ 61.45, 61.46, and 61.47, as applicable.

* * * * *

(c) Each price cap tariff filing that proposes rates above the applicable band limits established in §§ 61.47 (e), (g) and (h) must be accompanied by supporting materials establishing substantial cause for the proposed rates.

* * * * *

(l) Above the bottom margin of each page of cost support material submitted pursuant to this section, the carrier shall indicate the transmittal number under which that page was submitted.

§ 61.50 [Reserved]

37. Remove and reserve § 61.50.

38. Remove the undesignated center heading entitled ''Specific Rules for Tariff Publications'' immediately before § 61.51.

§ 61.51 [Reserved]

39. Remove and reserve § 61.51.

§ 61.53 [Redesignated]

40. Redesignate § 61.53 as § 61.83.

41. Amend § 61.54 by revising paragraph (b)(3), redesignating paragraph (c)(1) as paragraph (c)(1)(i), adding paragraph (c)(1)(ii), redesignating paragraph (c)(3) as paragraph (c)(3)(i), and adding paragraph (c)(3)(ii) to read as follows:

§ 61.54 Composition of tariffs.

* * * * *

(b) * * *

(3) *Expiration date.* Subject to § 61.59, when the entire tariff or supplement is to expire with a fixed date, the expiration date must be shown in connection with the effective date in the following manner. Changes in expiration date must be made pursuant to the notice requirements of § 61.58, unless otherwise authorized by the Commission.

Expires at the end of _____ (date) unless sooner canceled, changed, or extended.

* * * * *

(c) * * *

(1) * * *

(ii) Alternatively, the carrier is permitted to number its tariff pages, other than the check sheet, to reflect the section number of the tariff as well as the page. For example, under this system, pages in section 1 of the tariff would be numbered 1–1, 1–2, etc., and pages in section 2 of the tariff would be numbered 2–1, 2–2, etc. Issuing carriers shall utilize only one page numbering system throughout its tariff.

* * * * *

(3) * * *

(ii) Above the bottom margin of each page, the carrier shall indicate the transmittal number under which that page was submitted.

§ 61.55 [Redesignated]

42. Redesignate § 61.55 as § 61.85.

43. Redesignate § 61.56 as § 61.86, and revise it to read as follows:

§ 61.86 Supplements.

A carrier may not file a supplement except to suspend or cancel a tariff publication, or to defer the effective date of pending tariff revisions.

44. Redesignate § 61.57 as § 61.87, and revise to read as follows:

§ 61.87 Cancellation of tariffs.

(a) A carrier may cancel an entire tariff. Cancellation of a tariff automatically cancels every page and supplement to that tariff except for the canceling Title Page or first page.

(1) If the existing service(s) will be provided under another carrier's tariff, then

(i) the carrier whose tariff is being canceled must revise the Title Page or the first page of its tariff indicating that the tariff is no longer effective, or (ii) the carrier under whose tariff the service(s) will be provided must revise the Title Page or first page of the tariff to be canceled, using the name and numbering shown in the heading of the tariff to be canceled, indicating that the tariff is no longer effective. This carrier must also file with the Commission the new tariff provisions reflecting the service(s) being canceled. Both filings must be effective on the same date and may be filed under the same transmittal.

(2) If a carrier canceling its tariff intends to cease to provide existing service, then it must revise the Title Page or first page of its tariff indicating that the tariff is no longer effective.

(3) A carrier canceling its tariff, as described above, must comply with § 61.22 or §§ 61.54(b)(1) and 61.54(b)(5), as applicable.

(b) When a carrier cancels a tariff as described above, the canceling Title Page or the first page of the canceled tariff must show where all rates and regulations will be found except for paragraph (c) of this section. The Title Page or first page of the new tariff must indicate the name of the carrier and tariff number where the canceled material had been found.

(c) When a carrier ceases to provide service(s) without a successor, it must cancel its tariff pursuant to the notice requirements of § 61.23 or 61.58, as applicable, unless otherwise authorized by the Commission.

45. Amend § 61.58 as follows:

a. Redesignate paragraph (a)(2) as paragraph (a)(2)(iii), and add new paragraphs (a)(2)(i) and (ii);

b. Revise paragraph (a)(3);

c. Remove and reserve paragraph (b);

d. Amend paragraph (c) by removing the first sentence of paragraph (c)(1); removing and reserving paragraph (c)(4); revising paragraph (c)(5); removing and reserving paragraph (c)(6); revising paragraph (c)(7); and adding paragraph (c)(8);

e. Remove and reserve paragraph (d);

f. Amend paragraph (e) by revising the paragraph heading, redesignating paragraph (e)(3) as paragraph (e)(4), and adding new paragraph (e)(3); and

g. Remove and reserve paragraph (f).

§ 61.58 Notice requirements.

(a) * * *

(2) * * *

(i) Local exchange carriers may file tariffs pursuant to section 204(a)(3) of the Communications Act. Such a tariff may be filed on 7 days' notice if it proposes only rate decreases. Any other tariff filed pursuant to section 204(a)(3) of the Communications Act, including those that propose a rate increase or any change in terms and conditions, shall be filed on 15 days' notice. Any tariff filing made pursuant to section 204(a)(3) of the Communications Act must comply with the applicable cost support requirements specified in this part.

(ii) Local exchange carriers may elect not to file tariffs pursuant to section 204(a)(3) of the Communications Act. Any such tariffs shall be filed in accordance with the notice requirements specified elsewhere in this section.

* * * * *

(3) Tariff filings proposing corrections or voluntarily deferring the effective date of a pending tariff revision must be made on at least 3 days' notice, and may be filed notwithstanding the provisions of § 61.59. Corrections to tariff materials not yet effective cannot take effect before the effective date of the original material. Deferrals must take effect on or before the current effective date of the pending tariff revisions being deferred.

* * * * *

(b) [Reserved]

(c) * * *

(1) For annual adjustments to the PCI, API, and SBI values under §§ 61.45, 61.46, and 61.47, respectively, local exchange carrier tariff filings must be made on not less than 90 days' notice.

* * *

* * * * *

(4) [Reserved]

(5) Tariff filings involving a change in rate structure of a service included in a basket listed in § 61.42(d), or the introduction of a new service within the scope of § 61.42(g), must be made on at least 45 days' notice.

(6) [Reserved]

(7) The required notice for tariff filings involving services included in § 61.42(f), or tariff filings involving changes in tariff regulations, shall be that required in connection with such filings by dominant carriers that are not subject to price cap regulation.

(8) Carriers electing price cap regulation under § 61.41(a)(3) of this part in a year after 1991 shall file cost support for its initial price cap tariffs pursuant to § 61.49(k) of this chapter at least 90 days prior to July 1, and shall file its initial price cap tariff to be effective on July 1 of the year of election. Each PCI, API, and SBI shall be assigned an initial value prior to adjustment of 100, corresponding to the costs and rates in effect as of January 1 of the year of election.

(d) [Reserved]

(e) *Non-price cap carriers and/or services.* * * *

* * * * *

(3) Alascom, Inc. shall file its annual tariff revisions for its Common Carrier Services (Alascom Tariff F.C.C No. 11) on at least 90 days' notice.

* * * * *

(f) [Reserved]

46. Redesignate the text of § 61.59 as 61.59(a), revise redesignated paragraph (a), and add new paragraphs (b) and (c) to read as follows:

§ 61.59 Effective period required before changes.

(a) Except as provided in § 61.58(a)(3) or except as otherwise authorized by the Commission, new rates or regulations must be effective for at least 30 days before a dominant carrier will be permitted to make any change.

(b) Changes to rates and regulations that have not yet become effective, *i.e.*, are pending, may not be made unless the effective date of the proposed changes is at least 30 days after the scheduled effective date of the pending revisions.

(c) Changes to rates and regulations that have taken effect but have not been in effect for at least 30 days may not be made unless the scheduled effective date of the proposed changes is at least 30 days after the effective date of the existing regulations.

47. Designate §§ 61.67 through 61.74, and redesignated §§ 61.83, 61.85, 61.86, and 61.87, as subpart F, and add a subpart heading entitled ''Subpart F—Specific Rules for Tariff Publications of Dominant and Nondominant Carriers'' immediately preceding § 61.67.

48. Add § 61.66 to subpart F to read as follows:

§ 61.66 Scope.

The rules in this subpart apply to all carriers, unless otherwise noted.

§ 61.67 [Removed]

49. Remove § 61.67.

50. Revise § 61.69 to read as follows:

§ 61.69 Rejection.

When a tariff publication is rejected by the Commission, its number may not be used again. This includes, but is not limited to, such publications as tariff numbers or specific page revision numbers. The rejected tariff publication may not be referred to as either cancelled or revised. Within five business days of the release date of the Commission's Order rejecting such tariff publication, the issuing carrier shall file tariff revisions removing the rejected material, unless the Commission's Order establishes a different date for this filing. The publication that is subsequently issued in lieu of the rejected tariff publication must bear the notation.

In lieu of ____, rejected by the Federal Communications Commission.

51. Revise § 61.72 to read as follows:

§ 61.72 Public information requirements.

(a) Issuing carriers must make available accurate and timely information pertaining to rates and regulations subject to tariff filing requirements.

(b) Issuing carriers must, at a minimum, provide a telephone number for public inquiries about information contained in its tariffs. This telephone number should be made readily available to all interested parties.

52. Add new paragraphs (e) and (f) to § 61.74 to read as follows:

§ 61.74 References to other instruments.

* * * * *

(e) Tariffs may reference other FCC tariffs that are in effect and on file with the Commission for purposes of determining mileage, or specifying the operating centers at which a specific service is available.

(f) Tariffs may reference technical publications which describe the engineering, specifications, or other technical aspects of a service offering, provided the following conditions are satisfied:

(i) The tariff must contain a general description of the service offering, including basic parameters and structural elements of the offering;

(ii) The technical publication includes no rates, regulatory terms, or conditions which are required to be contained in the tariff, and any revisions to the technical publication do not affect rates, regulatory terms, or conditions included in the tariff, and do not change the basic nature of the offering;

(iii) The tariff indicates where the technical publication can be obtained;

(iv) The referenced technical publication is publicly available before the tariff is scheduled to take effect; and

(v) The issuing carrier regularly revises its tariff to refer to the current edition of the referenced technical publication.

53. Add § 61.77 to subpart F to read as follows:

§ 61.77 Combined domestic and international tariffs prohibited.

No tariff publication filed with the Commission may include rates, terms, or conditions for both domestic and international services.

54. Remove the undesignated center heading ''Concurrences'' immediately before § 61.131.

55. Designate §§ 61.131 through 61.136 as subpart G, and add a subpart heading entitled ''Subpart G—Concurrences'' immediately preceding § 61.131.

56. Amend § 61.132 by adding two sentences at the end of the section, to read as follows:

§ 61.132 Method of filing concurrences.

* * * Nondominant issuing carriers shall file revisions reflecting concurrences in their tariffs on the notice period specified in § 61.23 of this part. Dominant issuing carriers shall file concurrences in their tariffs on the notice periods specified in § 61.58(a)(2) or § 61.58(e)(1)(iii) of this part.

57. Remove the undesignated center heading ''Applications for Special Permission'' immediately preceding § 61.151.

58. Designate §§ 61.151 through 61.153 as subpart H, and add a subpart heading entitled ''Subpart H—Applications for Special Permission'' immediately preceding § 61.151.

59. Amend § 61.153(b) by revising paragraph (b) to read as follows:

§ 61.153 Method of filing applications.

* * * * *

(b) In addition, except for issuing carriers filing tariffing fees electronically, for all special permission applications requiring fees as set forth in part 1, subpart G of this chapter, the issuing carrier must submit the original of the application letter (without attachments), FCC Form 159, and the

appropriate fee to the Mellon Bank, Pittsburgh, PA at the address set forth in § 1.1105 of this chapter. Issuing carriers submitting tariff fees electronically should submit the Form 159 and the original cover letter to the Secretary of the Commission in lieu of the Mellon Bank. The Form 159 should display the Electronic Audit Code in the box in the upper left hand corner marked ''reserved.'' Issuing carriers should submit these fee materials on the same date as the submission in paragraph (a) of this section.

* * * * *

60. Remove the undesignated center heading ''Adoption of Tariffs and Other Documents of Predecessor Carriers'' immediately preceding § 61.171.

61. Designate §§ 61.171 through 61.172 as subpart I, and add a subpart heading entitled ''Subpart I—Adoption of Tariffs and Other Documents of Predecessor Carriers'' immediately preceding § 61.171.

62. Remove the undesignated center heading ''Suspensions'' immediately preceding § 61.191.

63. Designate §§ 61.191 through 61.193 as subpart J, and add a subpart heading entitled ''Subpart J—Suspensions'' immediately preceding § 61.191.

64. Revise § 61.191 to read as follows:

§ 61.191 Carrier to file supplement when notified of suspension.

If a carrier is notified by the Commission that its tariff publication has been suspended, the carrier must file, within five business days from the release date of the suspension order, a consecutively numbered supplement without an effective date, which specifies the schedules which have been suspended.

65. In addition to the amendments set forth above, in 47 CFR part 61, remove the words ''Chief, Tariff Review Branch'' and add, in their place, the words ''Chief, Tariff and Pricing Analysis Branch'' in the following places:

a. Section 61.32(c);
b. Section 61.33(a)(3);
c. Section 61.38(c)(1);
d. Section 61.49(g)(2)(i);
e. Section 61.153(c).

PART 63—EXTENSION OF LINES AND DISCONTINUANCE, REDUCTION, OUTAGE AND IMPAIRMENT OF SERVICE BY COMMON CARRIERS; AND GRANTS OF RECOGNIZED PRIVATE OPERATING AGENCY STATUS

66. The authority citation continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 154(j), 201–205, 403, and 533, unless otherwise noted.

67. Amend § 63.10 by revising paragraph (c)(1) to read as follows:

§ 63.10 Regulatory classification of U.S. international carriers.

* * * * *

(c) * * *

(1) File international service tariffs pursuant to § 61.28 of this chapter.

PART 69—ACCESS CHARGES

68. The authority citation continues to read as follows:

Authority: 47 U.S.C. 154, 201, 202, 203, 205, 218, 220, 254, 403.

§ 69.2 [Amended]

69. In § 69.2, remove and reserve paragraph (tt).

70. Amend § 69.3 to revise paragraph (a), revise the introductory text of paragraph (e), revise paragraph (e)(6), revise paragraph (f), revise paragraph (h), revise the introductory text of paragraph (i), and to remove and reserve paragraph (j), to read as follows:

§ 69.3 Filing of access service tariffs.

(a) Except as provided in paragraphs (g) and (h) of this section, a tariff for access service shall be filed with this Commission for a two-year period. Such tariffs shall be filed with a scheduled effective date of July 1. Such tariff filings shall be limited to rate level changes.

* * * * *

(e) A telephone company or group of telephone companies may file a tariff that is not an association tariff. Such a tariff may cross-reference the association tariff for some access elements and include separately computed charges of such company or companies for other elements. Any such tariff must comply with the requirements hereinafter provided:

* * * * *

(6) A telephone company or companies that elect to file such a tariff shall notify the association not later than December 31 of the preceding year, if such company or companies did not file such a tariff in the preceding biennial period or cross-reference association charges in such preceding period that will be cross-referenced in the new tariff. A telephone company or companies that elect to file such a tariff not in the biennial period shall file its tariff to become effective July 1 for a period of one year. Thereafter, such telephone company or companies must file its tariff pursuant to paragraphs (f)(1) or (f)(2) of this section.

* * * * *

(f) (1) A tariff for access service provided by a telephone company that is required to file an access tariff pursuant to § 61.38 of this Chapter shall be filed for a biennial period and with a scheduled effective date of July 1 of any even numbered year.

(2) A tariff for access service provided by a telephone company that may file an access tariff pursuant to § 61.39 of this Chapter shall be filed for a biennial period and with a scheduled effective date of July 1 of any odd numbered year. Any such telephone company that does not elect to file an access tariff pursuant to the § 61.39 procedures, and does not participate in the Association tariff, and does not elect to become subject to price cap regulation, must file an access tariff pursuant to § 61.38 for a biennial period and with a scheduled effective date of July 1 of any even numbered year.

(3) For purposes of computing charges for access elements other than Common Line elements to be effective on July 1 of any even-numbered year, the association may compute rate changes based upon statistical methods which represent a reasonable equivalent to the cost support information otherwise required under part 61 of this chapter.

* * * * *

(h) Local exchange carriers subject to price cap regulation as that term is defined in § 61.3(x) of this chapter, shall file with this Commission a price cap tariff for access service for an annual period. Such tariffs shall be filed to meet the notice requirements of § 61.58 of this Chapter, with a scheduled effective date of July 1. Such tariff filings shall be limited to changes in the Price Cap Indexes, rate level changes (with corresponding adjustments to the affected Actual Price Indexes and Service Band Indexes), and the incorporation of new services into the affected indexes as required by § 61.49 of this chapter.

(i) The following rules apply to the withdrawal from Association tariffs under the provision of paragraph (e)(6) or (e)(9) of this section or both by telephone companies electing to file price cap tariffs pursuant to paragraph (h) of this section.

* * * * *

§ 69.111 [Amended]

71. Amend § 69.111(g)(4), by removing ''§ 61.43(e)(2)(v)'' and adding, in its place, ''§ 61.42(e)(2)(v)'', and by removing ''§ 61.43(e)(2)(vi)'' and adding, in its place, ''§ 61.42(e)(2)(vi)''.

§ 69.113 [Amended]

72. In § 69.113(c), remove the word ''§ 61.3(v)'' and add, in its place, the word ''§ 61.3(x)''.

§ 69.114 [Amended]

73. In § 69.114(a), remove the word ''§ 61.3(v)'' and add, in its place, the word ''§ 61.3(x)''.

[FR Doc. 98–24742 Filed 9–15–98; 8:45 am]

BILLING CODE 6712–01–P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Part 1509 and 1552

[FRL–6158–6]

Acquisition Regulation: Contractor Performance Evaluations

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule with request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is amending the EPA Acquisition Regulation (EPAAR) (48 CFR Chapter 15) to revise its policy and procedures regarding the evaluation of contractor performance on EPA contracts and to establish an EPAAR clause to be used in solicitations and contracts with an estimated dollar value in excess of $100,000. This proposed rule applies to all large and small entities who perform or are interested in performing under EPA contracts.

DATES: Comments should be submitted not later than November 16, 1998.

ADDRESSES: Written comments should be submitted to the contact listed below at the following address: U.S. Environmental Protection Agency, Office of Acquisition Management (3802R), 401 M Street, SW, Washington, D.C. 20460. Comments will also be accepted on disks in WordPerfect 6.1 format or by electronic mail (E-mail) to: smith.frances@epamail.epa.gov. E-mail comments must be submitted as an ASCII file, avoiding the use of special characters and any form of encryption. No Confidential Business Information (CBI) should be submitted through E-mail.

FOR FURTHER INFORMATION CONTACT: Frances Smith, U.S. Environmental Protection Agency, Office of Acquisition Management, (3802R), 401 M Street, SW, Washington, D.C. 20460, Telephone: (202) 564–4368.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule implements the Office of Federal Procurement Policy (OFPP) Policy Letter 92–5, Past Performance Information. The OFPP Policy Letter requires Federal agencies to evaluate contractor performance on contracts over $100,000, to use past performance information in making responsibility determinations in both sealed bid and competitively negotiated procurements, and to specify past performance as an evaluation factor in solicitations for competitively negotiated contracts expected to exceed $100,000.

B. Executive Order 12866

This proposed rule is a significant regulatory action for the purposes of Executive Order 12866. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) has reviewed and issued OMB Clearance No. 9000–0142 for agencies to adhere to the OFPP Policy Letter 92–5.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) applies to this proposed rule, and the information collection request (ICR) in this proposed rule has been evaluated by the Office of Management and Budget (OMB). The Office of Information and Regulatory Affairs within OMB has issued OMB Clearance No. 9000–0142 for the collection of contractor performance information. Comments regarding Paperwork Reduction Act concerns should be sent to OMB (Attn: EPA Desk Officer). OMB is required to make a decision concerning the collection of information contained in the proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to EPA on the proposed rule.

D. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), whenever EPA is required to publish notice of general rulemaking, EPA must prepare an initial regulatory flexibility analysis (IRFA) describing the economic impact of the proposal on small entities, unless the Agency certifies that a proposed rule will not have a ''significant economic impact on a substantial number of small entities.'' As defined in RFA/SBREFA, small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. After consideration of the economic impacts of today's proposed rule on small entities, the Agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule merely formalizes EPA's contractor performance evaluation process, as an expansion of the government-wide requirements already established in the Federal Acquisition Regulation, 48 CFR Subpart 42.15. The proposed rule explains that EPA contracting officers will be recording the evaluations on simple and easy-to-understand report forms generated by the National Institutes of Health's (NIH) Contractor Performance System. Likewise, the evaluation rating system that the contracting officers will be using is based on straightforward numerical scores with a narrative explanation to be provided by the contracting officers. An adverse economic impact upon a contractor (i.e., in the form of less future federal business) as a result of a rating assessed by an EPA contracting officer would be attributable to the contractor's past performance itself, not to the rating system prescribed herein.

Further, the proposed rule requires no reporting or recordkeeping by contractors. Rather, the proposed rule merely provides contractors with a formal opportunity, generally one time a year per contract, to review and comment on their specific performance evaluations as conducted by the cognizant EPA contracting officers. EPA estimates that the contractor's review and comment process will require a minimal amount of time to complete; therefore, to the extent that this does result in some contractor-incurred costs, EPA anticipates that these will be de minimus. In any event, any reasonable costs incurred by the contractor in connection with the process will be allowable and allocable to the contract under evaluation and thereby borne by EPA.

E. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess their regulatory actions on State, local, and tribal governments, and the private sector. This proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in aggregate, or the private sector in one year. The rule is not

subject to the requirements of sections 202 and 205 of the UMRA.

F. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by E.O. 12866, and because it does not involve decisions on environmental health or safety risks.

List of Subjects in 48 CFR Parts 1509 and 1552

Environmental protection, Government procurement. Therefore, 48 CFR Chapter 15 is proposed to be amended as set forth below:

1. The authority citation for Parts 1509 and 1552 continue to read as follows:

Authority: 5 U.S.C. 301; Sec. 205(c), 63 Stat. 390, as amended.

PART 1509—[AMENDED]

2. Section 1509.170–1 is amended by adding the following at the end:

* * * Contracting officers shall insert the contract clause at 1552.209–76 in all solicitations and contracts with an estimated dollar value in excess of $100,000. For acquisitions involving options, the total estimated value of the acquisition shall include the estimated base amount plus the option(s) amount(s).

3. Sections 1509.170–2, 1509.170–3, and 1509.170–4 are revised to read as follows:

1509–170–2 Purpose.

This subpart provides guidance to program and contracting personnel regarding the evaluation of contractor performance. It establishes a uniform method for determining and recording the effectiveness of contractors in meeting contractual obligations. Additionally, this subpart details a systematic approach for identifying and maintaining records of contractors' performance histories.

1509.170–3 Applicability.

(a) This subpart applies to all EPA acquisitions in excess of $100,000, except for construction acquisitions, architect-engineer acquisitions, acquisitions awarded under FAR Subpart 8.6, Acquisitions from Federal Prison Industries, Incorporated, FAR Subpart 8.7, Acquisitions from Nonprofit Agencies Employing People Who Are Blind or Severely Disabled, and FAR 13.5, Test Program for Certain Commercial Items. FAR 36.201 and 36.604 provide detailed instructions for construction and architect-engineer contractor performance evaluations.

(b) The acquisition of commercial items in accordance with FAR 13.106 is not applicable to this subpart because simplified acquisition procedures do not require the creation or existence of a formal database for past performance evaluations. In cases where simplified acquisition procedures are not used to acquire commercial items (see FAR 12.203), this subpart is applicable to acquiring commercial items in excess of $100,000.

(c) EPA Form 1900–26, Contracting Officer's Evaluation of Contractor Performance, and EPA Form 1900–27, Project Officer's Evaluation of Contractor Performance, shall apply to all performance evaluations completed prior to the effective date of this subpart. However, on the effective date of this chapter, EPA Forms 1900–26 and 1900–27 are obsolete and all contractor performance evaluations shall be completed by use of the National Institutes of Health's (NIH) Contractor Performance System.

1509.170–4 Definitions.

(a) *Contractor Performance Report* is an evaluation of a contractor's performance for a specified period of time.

(b) *Interim Report* refers to a Contractor Performance Report that covers a contractor's performance evaluation at the end of each contract period of performance (including extensions to the performance period, but not exceeding 24 months) or each 12 month (from the date of contract award) performance period when the contract period of performance exceeds 24 months.

(c) *Final Report* refers to a Contractor Performance Report that covers the last period of performance in a contract. If the last period of performance exceeds 24 months, an interim Report shall be completed for 12 months (from the date of the prior performance evaluation) of contractor performance and the final (last) Report shall cover the remaining months of contractor performance.

(d) *Ratings* refer to the numerical scores for each performance category. Ratings are defined as follows: 0 = unsatisfactory, 1 = poor, 2 = fair, 3 = good, 4 = excellent, and 5 = outstanding.

(e) *Summary* ratings refer to the ratings determined by one level above the contracting officer (CO) regarding disagreements between the contractor and the CO. Summary ratings reflect the Agency's ultimate conclusion for the performance period being evaluated.

(f) *Performance Categories* refer to the measures used to evaluate a contractor's performance. Performance categories are defined as quality, cost control, timeliness of performance, and business relations.

4. Section 1509.170 is also amended by adding 1509.170–5, 1509.170–6, 1509.170–7, and 1509.170–8 to read as follows:

1509.170–5 Policy.

(a) Contracting officers (COs) are responsible for the timely completion of contractors' performance evaluations. The NIH Contractor Performance System shall be used to record individual contractor performance histories on EPA contracts and to obtain contractor past performance information for use in EPA's source selection process.

(b) Contracting officers are required to use the NIH Contractor Performance System to record evaluations for all contract performance periods expiring after the effective date of this subpart.

(c) Contractor evaluation information shall be recorded in Contractor Performance Reports (Report) which are generated by the NIH system. Reports shall cover individual contractor evaluations at the contract level, which includes all work assignments, task orders, or delivery orders associated with the period of performance being evaluated or the 12 month period being evaluated when the contract period of performance exceeds 24 months.

(d) The contracting officer (CO) must complete interim Reports covering each contract period of performance (including extensions to the performance period up to 24 months) or covering each 12 month period after contract award (if the contract period of performance exceeds 24 months) for all contracts in excess of $100,000, except those acquisitions identified in 1509.170–2 Applicability. In addition to interim Reports, the CO must complete a final Report which covers the last period of performance (including extensions to the last performance period up to 24 months) for applicable contracts in excess of $100,000. If the last period of performance exceeds 24

months, an interim Report shall be completed for 12 months (from the date of the prior performance evaluation) of contractor performance, and the final (last) Report shall cover the remaining months of contractor performance.

(e) The contracting officer (CO) shall initiate the process for completing interim Reports within five (5) calendar days after the end of each contract period of performance or at the end of each 12 month period if the contract period of performance exceeds 24 months. The CO shall initiate the process for completing a final Report within five (5) calendar days after the end of the last period of performance. Final Reports must be completed prior to contract closeout.

(f) The contracting officer (CO) must complete interim and final Reports, including the project officer's (PO) evaluation of contractor performance, receipt of any contractor input, and resolution of summary ratings (if any) within 90 calendar days from the date the CO initiates the evaluation.

(g) Reports shall be used to inform other agencies and departments (upon request) about a contractor's performance on an EPA contract, and to assist the contracting officer and the Technical Evaluation Panel (TEP) with evaluating past performance for future EPA acquisitions.

(h) When evaluating proposals, contracing officers (COs) shall use the NIH system to access Reports from other agencies or departments that are available in the NIH database. COs may need to access past performance information from other than the NIH system if the NIH system does not include applicable information.

(i) In accordance with FAR 42.1503(b), the ultimate conclusion on the performance evaluation is the decision of the Agency. The CO must ensure the accuracy of ratings for each performance category by verifying that information in the contract file corresponds with the PO's designated ratings. A contractor's performance evaluation should closely parallel award fee determinations made under the contract.

(j) In cases of novations involving successors-in-interest, a final evaluation of the predecessor contractor must be completed within five (5) calendar days after the end of the predecessor contractor's performance, and an interim evaluation of the successor contractor must be completed at the end of the specific period of performance or at the end of each 12 month period after the successor began performing. In cases of change-of-name agreements, the system shall be changed to reflect the new contractor's name.

(k) Contracting officers must inform the Office of Debarment and Suspension of any repetitive unsatisfactory or poor (a score of 0 or 1) ratings encountered by the contractor.

1509.170–6 Filing of forms.

The original copy of completed Contractor Performance Reports (interim and final) shall be filed in each individual contractor's official contract file. The NIH Contractor Performance System will retain all reports three (3) years after contract completion.

1509.170–7 Release of ratings.

(a) Agencies and departments who subscribe to NIH's Contractor Performance System will have direct access to all Reports, including those of EPA, in NIH's database. Information on EPA contractors' performance ratings may also be obtained by contacting the EPA contracting officer responsible for the evaluation.

(b) Contractors' performance ratings may be released to other Federal, State, and local Governments upon written request. The release to other Federal, State, and local Governments must stipulate that the information provided shall not be released outside of the requesting Government agency. In cases where the Federal agency is part of the NIH Contract Performance System, a written request is not applicable.

(c) The Department of Justice, Office of Information and Privacy, has concluded that past performance evaluations are exempt under Exemption 5 of the Freedom of Information Act (FOIA). However, any requests for contractor performance ratings by a third party (including, but not limited to commercial businesses (private industry) and foreign governments) must be processed in accordance with the FOIA and 40 CFR Part 2.

(d) FOIA requests shall be processed by the EPA FOIA office where the contract is located. The FOIA office will consult the Office of General Counsel, on a case-by-case basis, regarding applicable FOIA exemptions.

1509.170–8 Contractor Performance Report.

(a) Contractor Performance Reports (interim and final) must be prepared electronically by use of the NIH's Contractor Performance System. Hard copy preparation of Reports shall not be used unless specifically instructed by the NIH. NIH will provide EPA's Office of Acquisition Management Internal Oversight Service Center with specific instructions if hard copy use becomes necessary.

(b) A copy of the NIH Contractor Performance Report (including instructions) shall be included in each solicitation and contract with an estimated value in excess of $100,000.

PART 1552—[AMENDED]

5. Section 1552.2 is amended by adding 1552.209–76 as follows:

1552.209–76 Contractor Performance Evaluations.

As prescribed in section 1509.170–1, insert the following clause in all applicable solicitations and contracts.

CONTRACTOR PERFORMANCE EVALUATIONS

(OCT 19XX)

The contracting officer (CO) shall complete a Contractor Performance Report (Report) within ninety (90) calendar days after the end of each contract period of performance in accordance with EPAAR 1509.170–5. The contractor shall be evaluated based on the following ratings and performance categories:

Ratings: 0 = unsatisfactory, 1 = poor, 2 = fair, 3 = good, 4 = excellent, 5 = outstanding.

Performance Categories

Quality: Compliance with contract requirements; accuracy of reports; effectiveness of personnel; and technical excellence.

Rating	
0	Contractor is not in compliance and is jeopardizing achievement of contract objectives.
1	Major problems have been encountered.
2	Some problems have been encountered.
3	Minor inefficiencies/errors have been identified.
4	Contractor is in compliance with contract requirements and/or delivers quality products/services.
5	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance level described as ''Excellent.''

Cost Control: Record of forecasting and controlling target costs; current, accurate and complete billings; relationship of negotiated costs to actuals; cost efficiencies.

Rating	
0	Contractor is unable to manage costs effectively.
1	Contractor is having major difficulty managing costs effectively.
2	Contractor is having some problems managing costs effectively.

Rating	
3	Contractor is usually effective in managing costs.
4	Contractor is effective in managing costs and submits current, accurate, and complete billings.
5	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance level described as ''Excellent.''

Timeliness of Performance: Met interim milestones; reliability; responsive to technical direction; completed on time, including wrap-up and contract administration; met delivery schedules; no liquidated damages assessed.

Rating	
0	Contractor delays are jeopardizing performance of contract objectives.
1	Contractor is having major difficulty meeting milestones and delivery schedule.
2	Contractor is having some problems meeting milestones and delivery schedule.
3	Contractor is usually effective in meeting milestones and delivery schedule.
4	Contractor is effective in meeting milestones and delivery schedule.
5	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance level described as ''Excellent.''

Business Relations: Effective management, including subcontracts; reasonable/cooperative behavior; responsive to contract requirements; notification of problems; flexibility; pro-active versus reactive; effective small/small disadvantage business subcontracting program.

Rating	
0	Response to inquires, technical/service/administrative issues is not effective.
1	Response to inquiries, technical/service/administrative issues is marginally effective.
2	Response to inquiries, technical/service/administrative issues is somewhat effective.
3	Response to inquiries, technical/service/administrative issues is usually effective.
4	Response to inquiries, technical/service/administrative issues is effective.
5	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance level described as ''Excellent.''

(a) The contracting officer (CO) shall initiate the process for completing interim Reports within five (5) calendar days at the end of each contract period of performance or at the end of each 12 month contract period (if the contract period of performance exceeds 24 months) by requesting the project officer (PO) to evaluate contractor performance for the interim Report. In addition, the CO shall initiate the process for completing final Reports within five (5) calendar days after the end of the last period of performance (not exceeding 24 months) by requesting the project officer to evaluate contractor performance for the final Report. The final Report shall cover the last contract period of performance which may be less than 12 months, but not more than 24 months. Within thirty (30) calendar days after the PO receives a request from the CO to complete an evaluation, the PO shall:

(1) complete a description of the contract requirements;

(2) evaluate contractor performance and assign a rating for quality, cost control, and timeliness of performance categories (including a narrative for each rating);

(3) provide any information regarding subcontracts, key personnel, and customer satisfaction;

(4) assign a recommended rating for the business relations performance category (including a narrative for the rating); and

(5) provide additional information appropriate for the evaluation or future evaluations.

(b) The CO shall:

(1) ensure the accuracy of the PO's evaluation by verifying that the information in the contract file corresponds with the designated PO's ratings;

(2) assign a rating for the business relations performance category (including a narrative for the rating);

(3) concur with or revise the PO's ratings after consultation with the PO;

(4) provide any additional information concerning the quality, cost control, and timeliness of performance categories if deemed appropriate for the evaluation or future evaluations (if any), and provide any information regarding subcontracts, key personnel, and customer satisfaction; and

(5) forward the Report to the contractor within ten (10) calendar days after the CO receives the PO's evaluation.

(c) The contractor shall be granted thirty (30) calendar days from the date of the contractor's receipt of the Report to review and provide a response to the CO regarding the contents of the Report. The contractor shall:

(1) review the Report;

(2) provide a response (if any) to the CO on company letter head or electronically;

(3) complete contractor representation information; and

(4) forward the Report to the CO within the designated thirty (30) calendar days.

(d) The contractor's response to the Report may include written comments, rebuttals (disagreements), or additional information. If the contractor does not respond to the Report within the designated thirty (30) calendar days, the specified ratings in the Report are deemed appropriate for the reporting period of performance. In this instance, the CO shall complete the Agency review and sign the Report within three (3) calendar days after expiration of the specified 30 calendar days.

(e) If the contractor submits comments, rebuttals (disagreements), or additional information to the CO which contests the ratings, the CO, in consultation with the PO, shall initially try to resolve the disagreement(s) with the contractor.

(f) If the disagreement(s) is (are) not resolved between the contractor and the CO, the CO shall provide a written recommendation to one level above the CO for resolution as promptly as possible, but no later than five (5) calendar days after the CO is made aware that the disagreement(s) has (have) not been resolved with the contractor. The individual who is one level above the CO shall:

(1) review the CO's written recommendation; and

(2) provide a written determination to the CO for summary ratings (ultimate conclusion for ratings pertaining to the performance period being evaluated) within five (5) calendar days after the individual one level above the CO receives the CO's written recommendation.

(g) If the disagreement is resolved, the CO shall complete the Agency review and sign the Report within three (3) calendar days after consultation.

(h) The CO shall complete the Agency review and sign the Report within three (3) calendar days after the CO receives a written determination for summary ratings from one level above the CO.

(i) An interim or final Report is considered completed after the CO signs the Report. The CO must provide a copy of completed Reports (interim and final) to the contractor within two (2) calendar days after completion.

Dated: August 31, 1998.

Betty L. Bailey,

Director, Office of Acquisition Management.

BILLING CODE 6560–50–P

APPENDIX TO THE PREAMBLE - COPY OF THE NIH CONTRACTOR PERFORMANCE REPORT

National Institutes of Health

CONTRACTOR PERFORMANCE REPORT

FINAL REPORT _____ INTERIM REPORT _____ *(Check one)*

REPORTING PERIOD: *(from)* *(to)*

CONTRACTING OFFICE *(Location):*

CONTRACT NUMBER: **TASK NO:**

CONTRACTOR NAME:
ADDRESS:
CITY: **STATE:** **ZIP CODE:**

CONTRACT AWARD DATE:
CONTRACT EXPIRATION DATE:

CONTRACT VALUE: $

TIN:
SIC:
CONTRACT TYPE:

DESCRIPTION OF REQUIREMENT *(Title)*:

RATINGS

Summarize contractor performance and *circle* **the number which corresponds to the rating for each rating category.** *(See attached Rating Guidelines) At this time comments are limited to 2000 characters.*

QUALITY OF PRODUCT OR SERVICE **Rating: 0 1 2 3 4 5**
Comments:

COST CONTROL **Rating: 0 1 2 3 4 5**
Comments:

TIMELINESS OF PERFORMANCE **Rating: 0 1 2 3 4 5**
Comments:

BUSINESS RELATIONS **Rating: 0 1 2 3 4 5**
Comments:

SUBCONTRACTS

Are subcontracts involved? Yes No *(Circle one)*
Comments (*Please comment on those subcontractors that have provided a significant contribution to overall contract performance.)*

KEY PERSONNEL

PROJECT MANAGER/PRINCIPAL INVESTIGATOR *(name)*:
Comments:

KEY PERSON *(name)*:
Comments:

KEY PERSON *(name)*:
Comments:

CUSTOMER SATISFACTION

Is/was the contractor committed to customer satisfaction? Yes No *(Circle one)*
If this is the Final Report:
Would you recommend selection of this firm again? Yes No *(Circle one)*
Comments:

PROJECT OFFICER *(name)*:
SIGNATURE:_____
Phone: **FAX:**
Internet Address:
Date:

CONTRACTING OFFICER CONCURRENCE:*(Initial)* _____
Date:

CONTRACTOR'S REPRESENTATIVE *(name)*:
Phone: **FAX:**
Internet Address:
SIGNATURE:_____

SUMMARY RATINGS:

QUALITY: _____ **COST CONTROL:** _____

TIMELINESS OF PERFORMANCE: _____ **BUSINESS RELATIONS:** _____

CONTRACTING OFFICER *(name)*:
SIGNATURE: _____

Phone: **FAX:**
Internet Address:
Date:

CONTRACTOR'S REVIEW:

Were comments, rebuttal, or additional information provided?
Yes No *(Circle one)*
(If yes: They are:
On file in: _____ _____
(Location) *(Phone))*

Attached ____ *(Check if attached)*

AGENCY REVIEW:

Were contractor comments reviewed at a level above the contracting officer?
Yes No *(Circle one)*
(If yes: They are:
On file in: _____ _____
(Location) *(Phone))*
Attached _____ *(Check if attached)*

CONTRACTOR PERFORMANCE REPORT INSTRUCTIONS

TOP SECTION

1. Check the appropriate block to indicate the type of report (Interim, Final).
2. Indicate the period covered by the report.
3. List the name of the contracting officer and the location of the contracting office.
4. Identify the contract number of the contract being evaluated. Enter Task No. if applicable.
5. List the name and address of the contractor.
6. Enter TIN and SIC.
7. Enter Type of Contract (A - Fixed price re-determination; J - Firm fixed price; K - Fixed price with economic price adjustment; L - Fixed price incentive; R - Cost plus award fee; S - Cost no fee; T - Cost sharing; U - Cost plus fixed fee; V - Cost plus incentive fee; Y - Time and materials; Z - Labor hours)
8. Indicate the contract award date and contract expiration date.
9. State the contract value, including any option amounts.
10. Provide a brief description of the work being performed under the contract (the title of the contract).

RATINGS

Using the rating guideline, assign each area a rating of 0 (unsatisfactory), 1 (poor), 2 (fair), 3 (good), 4 (excellent), or 5 (outstanding). Provide a brief narrative (*2000 characters or less*) for each of the categories to support the rating assigned. The categories are: quality of product or service, cost control, timeliness of performance, and business relations.

SUBCONTRACTORS

Indicate whether subcontracts are/were involved. Briefly summarize (*2000 characters or less*) the performance of any subcontractors that have major responsibilities under the contract or are required to perform a significant part of the contract requirement. This space may also be used to evaluate a prime contractor's management of a subcontractor.

KEY PERSONNEL

List the name of the project manager/principal investigator (required) and the names of two other key personnel (optional). Briefly describe the performance of the key personnel listed. (*2000 characters or less*)

CUSTOMER SATISFACTION

Circle the appropriate answer to indicate whether the contractor was committed to customer satisfaction. For the final report, indicate whether you would recommend selection of the firm again.

PROJECT OFFICER SIGNATURE

The project officer signs this block.

CONTRACTING OFFICER CONCURRENCE

The contracting officer initials this block, indicating concurrence with the initial rating.

CONTRACTOR'S REPRESENTATIVE

The contractor signs this next block, indicating review of the rating.

SUMMARY RATINGS

Indicate the rating given for each of the rating categories: quality of goods or services, cost control, timeliness of performance, and business relations.

CONTRACTING OFFICER SIGNATURE

The contracting officer signs the report when all actions are completed. If changes were made to the ratings or the narrative during the rebuttal process, a copy of the report, as revised, shall be promptly furnished to the contractor.

CONTRACTOR'S REVIEW

Indicate whether the contractor submitted a rebuttal or comments. Attach a copy of the contractor's rebuttal to this report, or indicate its location, if filed separately.

AGENCY REVIEW

If the contracting officer and the contractor are unable to agree on a final rating, the matter is to be referred to an individual one level above the contracting officer. Attach a copy of the agency's decision to this report, or indicate its location, if filed separately.

[FR Doc. 98–24739 Filed 9–15–98; 8:45 am]
BILLING CODE 6560–50–C

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Extension of Public Comment Period for Take Guidance and Survey Protocol for the Cactus Ferruginous Pygmy-owl

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Extension on two public comment periods.

SUMMARY: The U.S. Fish and Wildlife Service (Service) provides notice that the public comment period is extended until November 14, 1998 for take guidance and survey protocol for the cactus ferruginous pygmy-owl.

DATES: Written comments should be received by November 14, 1998.

ADDRESSES: Persons wishing to review either the cactus ferruginous pygmy-owl take guidance or survey protocol may access either at the world wide web site of the Southwest Region of the Service at http://ifw2es.fws.gov/arizona/, or obtain copies by contacting the U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office, 2321 W. Royal Palm Road, Suite 103, Phoenix, Arizona 85021–4951 or by calling the Field Office at (602) 640–2720. Documents will also be available for public inspection by written request, by appointment only, during normal business hours (7:30 to 4:30), U.S. Fish and Wildlife Service, Phoenix, Arizona. Written data or comments concerning the cactus ferruginous pygmy-owl take guidance or survey protocol should be submitted to the Field Supervisor, Arizona Ecological Services Field Office, Phoenix, Arizona (see address above).

FOR FURTHER INFORMATION CONTACT: Tom Gatz, Acting Field Supervisor, Arizona Ecological Services Field Office in Phoenix, Arizona at (602) 640–2720.

SUPPLEMENTARY INFORMATION:

Background

The cactus ferruginous pygmy-owl was listed by the Service as an endangered species in Arizona on March 10, 1997 (62 FR 10730), based on extensive population declines within its historic range in the state. The pygmy-owl, a small reddish-brown owl, nests in a cavity in a tree or large columnar cactus. The species was once common to abundant in riparian forests, mesquite-cottonwood woodlands, and desertscrub habitats in central and southern portions of the state. It is still considered a potential inhabitant of riparian areas, where this extremely limited vegetative community still occurs, and is found in upper Sonoran Desert habitats usually consisting of dense ironwood, mesquite, acacia, bursage, and saguaro cacti, with understory vegetation of smaller trees and shrubs.

On August 13, 1998 (63 FR 43362 and 43363) the service published notices of availability and opening of public comment period for survey protocol and taking guidance.

Take Guidance

Urban and suburban development within the remaining appropriate habitat of the pygmy-owl is ongoing. These and other actions may result in take of the species. The Endangered Species Act and implementing regulations found at 50 CFR 17.21 and 17.31 set forth a series of general prohibitions that apply to all endangered and threatened wildlife, respectively. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect or to attempt any of these). Regulations at 50 CFR 17.3 define the terms ''harm'' and ''harass'' as used under the definition of ''take.'' ''Harm'' is defined as an act which actually kills or injures wildlife. Such acts may include significant habitat modification that impairs essential behavioral patterns, including breeding, feeding, or sheltering. ''Harass'' is defined as an intentional or negligent act or omission which creates a likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavior patterns, including, but not limited to, breeding, feeding, or sheltering.

Permits may be issued to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in connection with otherwise lawful activities.

At the time of listing the owl, the Service provided a partial listing of activities that could potentially harm, harass, or otherwise take the pygmy-owl. These included—

(1) Removal of nest trees;

(2) Removal of a nest box in use by the pygmy-owl;

(3) Clearing or significant modification of occupied habitat, whether or not the nest tree is included;

(4) Sustained noise disturbance during the breeding season;

(5) Pursuit or harassment of individual birds;

(6) Frequent or lengthy low-level flights over occupied habitat during the breeding season;

(7) Severe overgrazing that results in the removal of understory vegetation.

In furtherance of the Service's policy to provide information concerning what activities may be considered take of the pygmy-owl, the Service is making available information to aid both Federal and non-Federal entities in determining when a take situation may occur.

Survey Protocol

The Fish and Wildlife Service (Service), in cooperation with the Arizona Game and Fish Department (Department), propose a survey protocol for determining the presence of the endangered cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*) within known historic range of the species in Arizona. The proposed survey protocol comes in two versions depending on its use: the first is for use in determining if cactus ferruginous pygmy-owls are present on specific project sites where an activity is proposed; the second is for use in gathering information on distribution, occurrence, and numbers of pygmy-owls over more extensive areas of its historic range in Arizona. This proposed protocol is founded on procedures established by the Arizona Game and Fish Department in 1993. The proposed protocol incorporates modifications found to be appropriate following 5 years of field application. Differences between the 1993 protocol and the current proposed protocol include a reduction in the survey period from 9 months (September through May) to 6 months (January through June); and an increase in surveys from one to three, with 30 days between each of the three surveys preferred, but a minimum of 15 days required. At least one survey must occur between February 15 and April 15. In reviewing determinations of pygmy owl presence or absence, the Service will require the implementation of the protocol for two consecutive years (rather than one year) prior to actions that may impact the owls or their habitats.

The existing protocol will remain in use (i.e., surveys from September through December this year will still be accepted through December 31, 1998). Use of the currently proposed protocol will be required from January 1, 1999, forward.

The Service and Department have submitted the protocol to recognized species and technical experts for peer review to ensure a scientifically sound basis for determination of the presence of the species within its known range.

The Service and the Department will regularly review and modify, as necessary, the survey protocol to ensure that the best available scientific information is incorporated into the prescribed methodology.

Overall Purpose

The Service is extending the public comment period to ensure that adequate time is available for the public to provide additional information to more adequately understand the occurrence and biology of the cactus ferruginous pygmy-owl in central and southern Arizona. Until more complete scientific information is available, the Service believes that the use of the take guidance document and the proposed survey protocol document will protect the pygmy-owl while allowing carefully considered development to proceed and will provide the most biologically valid data upon which to determine habitat use and occupancy by the pygmy-owl.

Author

The primary author of this document is Tom Gatz, Acting Field Supervisor, Arizona Ecological Services Field Office (see **ADDRESSES** section).

Authority

The authority for this action is the Endangered Species Act (16 U.S.C. 1532 *et seq.*).

Dated: September 8, 1998.

Nancy M. Kaufman,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 98–24776 Filed 9–14–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 090898D]

RIN 0648-AK12

Fisheries of the Exclusive Economic Zone Off Alaska; Amendment 51 to the Fishery Management Plan for Groundfish of the Gulf of Alaska and Amendment 51 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendment 51 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI) and Amendment 51 to the Fishery Management Plan for Groundfish of the Gulf of Alaska (GOA) (FMPs). BSAI Amendment 51 would establish the following allocations and management measures for a 3-year period beginning in January 1999. Comments from the public are requested.

DATES: Comments on Amendments 51/51 must be submitted on or before November 16, 1998.

ADDRESSES: Comments on Amendments 51/51 should be submitted to Sue Salveson, Assistant Regional Administrator for Sustainable Fisheries, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Gravel, or delivered to the Federal Building, 709 West 9th Street, Juneau, AK. Copies of Amendments 51/51 and the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis prepared for Amendments 51/51 are available from the North Pacific Fishery Management Council at 605 West 4th Ave., Room 306, Anchorage, AK 99501, telephone 907–271–2809.

FOR FURTHER INFORMATION CONTACT: Kent Lind, 907-586-7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires that each Regional Fishery Management Council submit any fishery management plan (FMP) or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, immediately publish a document announcing that the FMP or amendment is available for public review and comment. NMFS will consider the public comments received during the comment period in determining whether to approve the FMP or amendment.

BSAI Amendment 51

At its June 1998 meeting, the Council voted 7–4 to adopt BSAI Amendment 51. This amendment, if approved, would make three significant changes to the existing BSAI inshore/offshore pollock allocation provisions: (1) Four percent of the BSAI pollock TAC, after subtraction of reserves, would be shifted to the inshore component resulting in a 39/61 inshore/offshore allocation split; (2) a portion of the inshore component Bering Sea B season allocation, equal to 2.5 percent of the BSAI pollock TAC after subtraction of reserves, would be set aside for small catcher vessels, and would become available on or about August 25 of each year; (3) catcher vessels delivering to the offshore component would be prohibited from fishing inside the CVOA during the B season from September 1 until the inshore component is closed to directed fishing. Amendment 51 would remain in effect for the years 1999 through 2001.

At its June 1998 meeting, the Council voted unanimously to adopt GOA Amendment 51. GOA Amendment 51, if approved, would allocate 100 percent of the GOA pollock TAC and 90 percent of the GOA Pacific cod TAC to vessels catching pollock and Pacific cod for processing by the inshore component. Ten percent of the GOA Pacific cod TAC would be allocated to vessels catching Pacific cod for processing by the offshore component.

A major concern identified during the preliminary review of Amendments 51/51 is that the economic analysis submitted by the Council does not provide a basis upon which to draw unambiguous conclusions about the probable net economic benefits of the competing alternatives. Treated in considerable detail in the document, the reasons for this deficiency pertain to basic data limitations that make conversion from gross to net economic measures impossible.

Completion of the preliminary review with publication of the notice of availability (NOA) for Amendments 51/51 does not mean that either of these two amendments will be approved.

NMFS invites comment on the consistency of the amendments with the provisions of the Magnuson-Stevens Act, the national standards, and other applicable laws. Comments are specifically requested on the adequacy of the analysis to support findings of compliance with national standards 2 (scientific information), 4 (allocations), 5 (efficiency), 7 (costs and benefits), 8 (fishing communities), and 10 (safety of life at sea). Information and analysis that bolster or contradict the conclusions in any of the supporting documents are also welcome.

NMFS will consider the public comments received during the comment period in determining whether to approve Amendments 51/51. A proposed rule to implement Amendments 51/51 is scheduled to be published within 15 days of this document.

Public comments are being solicited on the amendments through the end of the comment period stated in this NOA; a proposed rule that would implement the amendments may be published in the **Federal Register** for public comment following NMFS' evaluation under the Magnuson-Stevens Act procedures. Public comments on the proposed rule must be received by the end of the comment period on the amendments to be considered in the approval/disapproval decision on the amendments. All comments received by the end of the comment period on the amendments, whether specifically directed to the amendments or the proposed rule, will be considered in the approval/disapproval decision; comments received after that date will not be considered in the approval/disapproval decision on the amendments. To be considered, comments must be *received* by close of business on the last day of the comment period specified in this NOA; that does not mean postmarked or otherwise transmitted by that date.

Dated: September 10, 1998.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–24847 Filed 09–15–98; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 63, No. 179
Wednesday, September 16, 1998

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 11, 1998.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503 *and* to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, D.C. 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–6746.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Development

Title: Rural Empowerment Zones and Enterprise Communities (Application Process).

OMB Control Number: 0570–0026.

Summary of Collection: The Taxpayer Relief Act of 1997 amended the Internal Revenue Code to authorize the Secretaries of the Housing Urban Development (HUD) and Department of Agriculture (USDA) to designate, respectively, 15 more urban and 5 more rural empowerment zones. Two sets of data are needed to comply with the statutory requirements; application data and ongoing reporting data. Rural Development (RD) will collect information using several reports.

Need and Use of the Information: RD will collect information on poverty by census tract, unemployment and economic/social distress, overall population by tract, and geographic data as to size and configuration from applicants as a means of evaluating and selecting potential empowerment zones and enterprise communities. Applying for designation as an empowerment zone or enterprise community is a one-time process.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 75.

Frequency of Responses: Reporting: Other (One time).

Total Burden Hours: 3,750.

Rural Development

Title: Rural Empowerment Zones and Enterprise Communities (Ongoing Reporting Requirements).

OMB Control Number: 0570–0027.

Summary of Collection: The Taxpayer Relief Act of 1997 amended the Internal Revenue Code to authorize the Secretaries of the Housing Urban Development (HUD) and Department of Agriculture (USDA) to designate, respectively, 15 more urban and 5 more rural empowerment zones. Two sets of data are needed to comply with the statutory requirements; application data and ongoing reporting data. Rural Development (RD) will collect information using several reports.

Need and Use of the Information: Once selected, the designees' progress reports provide management information for USDA, oversight information for the Vice President's Community Empowerment Board, and status reporting for Congress. The periodic reviews also provide the basis for USDA to continue or revoke a designation during the 10-year life of the federal program.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 38.

Frequency of Responses: Reporting: Semi-annually; Annually.

Total Burden Hours: 761.

Agricultural Research Service

Title: Patent License Application.

OMB Control Number: 0518–0003.

Summary of Collection: The USDA Patent Licensing Program grants patent licenses to qualified businesses and individuals who wish to commercialize inventions arising from federally supported research. The Agricultural Research Service (ARS) oversees licensing of federally owned inventions which must be done in accordance with the terms, conditions, and procedures prescribed under 37 CFR Part 404. Application information must be collected to identify the business or individual desiring the patent license along with a plan for the development and marketing of the invention and a description of the applicant's ability to fulfill the plan.

Need and Use of the Information: ARS will collect identifying information on the applicant, identifying information for the business, and a detailed description for development and/or marketing of the invention using form AD–761. The information collected is used to determine whether the applicant has both a complete and sufficient plan for developing and marketing the invention and the necessary manufacturing, marketing, technical, and financial resources to carry out the submitted plan.

Description of Respondents: Business or other for-profit; Individuals or households: Not-for-profit institutions; Farms; Federal Government; State, Local or Tribal Government.

Number of Respondents: 75.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 225.

Grain Inspection, Packers and Stockyards Administration

Title: Guidelines for Preparation of Research Proposal.

OMB Control Number: 0580–0014.

Summary of Collection: The Grain Inspection, Packers and Stockyards Administration (GIPSA) is responsible for establishment of grain standards which accurately describe the quality of grain being traded and for the uniform application of these standards in a nationwide inspection system. This authority is provided under Section 4a of the U.S. Grain Standards Act (USGSA). GIPSA maintains an external research program under which research scientists are invited to submit research grant proposals which include the objectives of the proposed work; application of the proposed work to the grain inspection system; the procedures, equipment, personnel, etc., that will be used to reach the project objectives; the cost of the project; a schedule for completion; qualifications of the investigator and the grantee organization; and a listing of all other sources of financial support for the project. GIPSA will collect information from research grant proposals.

Need and Use of the Information: GIPSA collects information on the technical capabilities of project personnel and the submitting organization, past experience of project personnel and the submitting organization, clarity of the proposal, technical feasibility of the solution to the problem, ease of application of the solution to use in the grain inspection system and the cost effectiveness of the research approach.

Description of Respondents: State, Local or Tribal Government; Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 3.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 60.

Nancy Sternberg,

Departmental Information Clearance Officer.

[FR Doc. 98–24766 Filed 9–15–98; 8:45 am]

BILLING CODE 3410–01–M

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Municipal Interest Rates for the Fourth Quarter of 1998

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of municipal interest rates on advances from insured electric loans for the fourth quarter of 1998.

SUMMARY: The Rural Utilities Service hereby announces the interest rates for advances on municipal rate loans with interest rate terms beginning during the fourth calendar quarter of 1998.

DATES: These interest rates are effective for interest rate terms that commence during the period beginning October 1, 1998, and ending December 31, 1998.

FOR FURTHER INFORMATION CONTACT: Carolyn Dotson, Loan Funds Control Assistant, U.S. Department of Agriculture, Rural Utilities Service, Room 0227–S, Stop 1524, 1400 Independence Avenue, SW, Washington, DC 20250–1500. Telephone: 202–720–1928. FAX: 202–690–2268. E-mail: CDotson@rus.usda.gov.

SUPPLEMENTARY INFORMATION: The Rural Utilities Service (RUS) hereby announces the interest rates on advances made during the fourth calendar quarter of 1998 for municipal rate electric loans. RUS regulations at 7 CFR 1714.4 state that each advance of funds on a municipal rate loan shall bear interest at a single rate for each interest rate term. Pursuant to 7 CFR 1714.5, the interest rates on these advances are based on indexes published in the ''Bond Buyer'' for the four weeks prior to the third Friday of the last month before the beginning of the quarter. The rate for interest rate terms of 20 years or longer is the average of the 20 year rates published in the Bond Buyer in the four weeks specified in 7 CFR 1714.5(d). The rate for terms of less than 20 years is the average of the rates published in the Bond Buyer for the same four weeks in the table of ''Municipal Market Data—General Obligation Yields'' or the successor to this table. No interest rate may exceed the interest rate for Water and Waste Disposal loans.

The table of Municipal Market Data includes only rates for securities maturing in 1998 and at 5 year intervals thereafter. The rates published by RUS reflect the average rates for the years shown in the Municipal Market Data table. Rates for interest rate terms ending in intervening years are a linear interpolation based on average of the rates published in the Bond Buyer. All rates are adjusted to the nearest one eighth of one percent (0.125 percent) as required under 7 CFR 1714.5(a). The market interest rate on Water and Waste Disposal loans for this quarter is 5.000 percent.

In accordance with 7 CFR 1714.5, the interest rates are established as shown in the following table for all interest rate terms that begin at any time during the fourth calendar quarter of 1998.

Interest rate term ends in (year)	RUS rate (0.000 percent)
2019 or later	5.000
2018	5.000
2017	5.000
2016	5.000
2015	4.875
2014	4.875
2013	4.875
2012	4.750
2011	4.625
2010	4.625
2009	4.500
2008	4.375
2007	4.375
2006	4.375
2005	4.250
2004	4.250
2003	4.250
2002	4.125
2001	3.875
2000	3.750
1999	3.500

Dated: September 8, 1998.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 98–24765 Filed 9–15–98; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 351.213 of the Department of Commerce (the Department) Regulations (19 CFR 351.213 (1997)), that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended of investigation.

Opportunity To Request a Review

Not later than the last day of September, interested parties may request administrative review of the following orders, findings, or suspended

investigations, with anniversary dates in September for the following periods:

	Period
Antidumping Duty Proceedings	
Argentina: Silicon Metal, A–357–803	9/1/97–8/31/98
Canada:	
Steel Jacks, A–122–006	9/1/97–8/31/98
New Steel Rail, Except Light Rail, A–122–804	9/1/97–8/31/98
Germany: Newspaper Printing Presses, A–428–821	9/1/97–8/31/98
Japan: Newspaper Printing Presses, A–588–837	9/1/97–8/31/98
Taiwan: Chrome-Plated Lug Nuts, A–583–810	9/1/97–8/31/98
The People's Republic of China:	
CDIW Fittings & Glands, A–570–820	9/1/97–8/31/98
Freshwater Crawfish Tail Meat, A–570–848	3/26/97–8/31/98
Greige Polyester/Cotton Printcloth, A–570–101	9/1/97–8/31/98
Chrome-Plated Lug Nuts, A–570–808	9/1/97–8/31/98
Countervailing Duty Proceedings	
Canada: New Steel Rail, Except Light Rail, C–122–805	1/1/97–12/31/97
Suspension Agreements	
None	

In accordance with section 351.213 of the regulations, an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. In revisions to its regulations, the Department changed its requirements for requesting reviews for countervailing duty orders. Pursuant to 771(9) of the Act, an interested party must specify the individual producers or exporters covered by the order or suspension agreement for which they are requesting a review (Department of Commerce Regulations, 62 FR 27295, 27494 (May 19, 1997)). Therefore, for both antidumping and countervailing duty reviews, the interested party must specify for which individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room 1870, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Sheila Forbes, in room 3065 of the main Commerce Building. Further, in accordance with section 351.303(f)(1)(i) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of September. If the Department does not receive, by the last day of September, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute but is published as a service to the international trading community.

Dated: August 28, 1998.

Maria Harris Tildon,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 98–24748 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–701]

Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On May 11, 1998, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on brass sheet and strip from the Netherlands (63 FR 75821). This review covers sales to the United States by one manufacturer/exporter, Outokumpu Copper Strip B.V. (OBV), and its U.S. affiliate, Outokumpu Copper (USA), Inc., of the subject

merchandise during the period of review (POR), August 1, 1996, through July 31, 1997. We gave interested parties an opportunity to comment on our preliminary results. We have not changed the results from those presented in the preliminary results of review.

FOR FURTHER INFORMATION CONTACT: Karla Whalen or Lisette Lach, Office of Antidumping/Countervailing Duty Enforcement, Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–1386 or (202) 482–6412, respectively.

EFFECTIVE DATE: September 16, 1998.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations last codified at 19 CFR Part 351 (May 19, 1997).

Scope of This Review

Imports covered by this review are brass sheet and strip, other than leaded and tin brass sheet and strip, from the Netherlands. The chemical composition of the products under review is currently defined in the Copper Development Association (CDA) 200 Series or the Unified Numbering System (UNS) C20000 series. This review does not cover products the chemical composition of which are defined by other CDA or UNS series. The physical dimensions of the products covered by this review are brass sheet and strip of solid rectangular cross section over 0.006 inch (0.15 millimeter) through 0.188 inch (4.8 millimeters) in gauge, regardless of width. Coiled, wound-on-reels (traverse-wound), and cut-to-length products are included. The merchandise under review is currently classifiable under items numbers 7409.21.00 and 7409.29.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under review is dispositive.

Background

On August 12, 1988, the Department published in the **Federal Register** the antidumping duty order on brass sheet and strip (BSS) from the Netherlands (53 FR 30455). On August 4, 1997, the Department published the notice of ''Opportunity to Request Administrative Review'' for the period August 1, 1996 through July 31, 1997 on BSS from the Netherlands (62 FR 41925).

On August 29, 1997, in accordance with 19 FR 351.213(b), OBV filed a letter requesting an administrative review of its sales in this period of review. On September 25, 1997, we published in the **Federal Register** a notice of initiation of this administrative review (62 FR 50292). On October 23, 1997, petitioners in this proceeding [1] entered a notice of appearance in this administrative review. On May 11, 1998, the Department published in the **Federal Register** the preliminary results of the administrative review (63 FR 25,821).

On May 18, 1998, the petitioners requested that the Department conduct a hearing on this administrative review. On June 10, 1998, petitioners withdrew their request for a hearing in this case and thus no hearing was held. On June 10, 1998, petitioners submitted their comments on this review and on June 16, 1998, OBV submitted its response to petitioners comments. The Department has now completed this administrative review in accordance with section 751 of the Act.

Analysis of Comments Received

Comment: Anticipated Revocation Request

Petitioners claim that OBV's sales response in this review indicates that OBV is likely to request a revocation of the order on BSS in the near future. Petitioners base this claim on the small volume of OBV's sales during this review at a non-dumping rate as compared to the large volume of OBV's sales prior to the imposition of the antidumping duty order. Petitioners state that during this review OBV had sales of roughly 18,000 pounds in contrast to exports of brass sheet and strip to the United States for the four calendar years preceding imposition of the antidumping duty order on BSS which were 15.6 million pounds in 1984, 15.4 million pounds in 1985, 14.9 million pounds in 1986, and 15.4 million pounds in 1987. Petitioners anticipate that OBV could base a revocation request on a claim of the absence of dumping on the small number of post-order sales. Petitioners go on to cite a number of recent cases in which the Department declined to revoke an order. Petitioners ask the Department to discuss how it would view this review in regards to a future revocation request by OBV.

In response to this comment, OBV argues that petitioners comment is irrelevant to this proceeding and should be disregarded by the Department since no party to this review has requested revocation of the order. Further, respondents claim that all the facts necessary to examine such an issue are not on the record.

Department's Position: While the Department recognizes the information provided by petitioner may be relevant to a revocation determination under section 353.222, it is not relevant to the current proceeding since no party to this order has requested a revocation of the order on BSS. Petitioners have also stated that revocation is not at issue in this proceeding.

Final Results of Review

As a result of this review, we have determined that the following margin exists for the period August 1, 1996 through July 31, 1997:

Producer/manufacturer/exporter	Weighted-average margin (percent)
Outokumpu Copper Strip B.V. (OBV)	0.00

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentage stated above. The Department will issue appraisement instructions directly to the U.S. Customs Service. Furthermore, the following deposit requirements shall be effective upon publication of this notice of final results of review for all shipments of the subject merchandise from the Netherlands entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) the cash deposit rates for OBV will be the rate as stated above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the

[1] Hussey Copper, Ltd.; The Miller Company; Olin Corporation; Revere Copper Products, Inc.; International Association of Machinists and Aerospace Workers; International Union, Allied Industrial Workers of America (AFL–CIO); Mechanics Educational Society of America (Local 56); and United Steelworkers of America (AFL–CIO/CLC).

manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash rate will be 16.99 percent, which was the ''all others'' rate as established in the LTFV investigation. The deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a final reminder to importers of their responsibility under 19 CFR section 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305[2] of the Department's regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and this notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1).

Dated: September 4, 1998.

Joseph Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 98–24746 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–815]

Initiation of Antidumping Duty Investigation: Elastic Rubber Tape From India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 16, 1998.

FOR FURTHER INFORMATION CONTACT: Craig Matney or Cynthia Thirumalai at (202) 482–1778 and (202) 482–4087, respectively, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

Initiation of Investigation

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR Part 351 (1998).

The Petition

On August 18, 1998, the Department of Commerce (the Department) received a petition filed in proper form by Fulflex, Inc., Elastomer Technologies Group, Inc., and RM Engineered Products, Inc., collectively referred to hereinafter as ''the petitioners.'' Elastomer and RM are both wholly owned subsidiaries of M-Tec Corporation. The petitioners filed supplemental information to the petition on September 1, 1998.

In accordance with section 732(b) of the Act, the petitioners allege that imports of elastic rubber tape (ERT) from India are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring an industry in the United States.

The Department finds that the petitioners filed this petition on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated that they are the only producers of ERT in the United States (*see* Determination of Industry Support for the Petition section below).

Scope of the Investigation

For purposes of this investigation, the product covered is elastic rubber tape. Elastic rubber tape is defined as vulcanized, non-cellular rubber strips, of either natural or synthetic rubber, 0.006 inches to 0.100 inches (0.15 mm to 2.54 mm) in thickness, and ⅛ inches to 1⅝ inches (3 mm to 42 mm) in width. Such product is generally used in swimwear and underwear.

The merchandise subject to this investigation is classified in the *Harmonized Tariff Schedule of the United States* (HTSUS) at subheading 4008.21.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

During our review of the petition, we discussed the scope with the petitioners to insure the petition accurately reflects the product for which they are seeking relief. Moreover, as discussed in the preamble to the new regulations (62 FR 27323), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments by September 29, 1998. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of our preliminary determination.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) at least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether the petition has the requisite industry support, the statute directs the Department to look to producers and workers who account for production of the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information.

[2] *See Antidumping and Countervailing Duty Proceedings: Administrative Protective Order Procedures; Procedures for Imposing Sanctions for Violation of a Protective Order* (63 FR 24391, May 4, 1998).

Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1] Section 771(10) of the Act defines the domestic like product as ''a product that is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' i.e., the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

The domestic like product referred to in the petition is the single domestic like product defined in the ''Scope of Investigation'' section, above. The Department has no basis on the record to find this definition of the domestic like product to be inaccurate. The Department, therefore, has adopted this domestic like product definition.

In this case, the Department has determined that the petition and supplemental information contained adequate evidence of sufficient industry support; therefore, polling was not necessary. *See* Initiation Checklist, dated September 8, 1998 (public document on file in the Central Records Unit of the Department of Commerce, Room B–099). Additionally, no person who would qualify as an interested party pursuant to section 771(A), (C), (D), (E) or (F) has expressed opposition on the record to the petition. To the best of the Department's knowledge, the producers who support the petition account for 100 percent of the production of the domestic like product. Accordingly, the Department determines that this petition is filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

Export Price and Normal Value

The following is a description of the allegation of sales at less than fair value upon which our decision to initiate this investigation is based. Should the need arise to use any of this information in our preliminary or final determination for purposes of facts available under section 776 of the Act, we may re-examine the information and revise the margin calculations, if appropriate.

The petitioners identified Garware as the only Indian exporter to the United States of ERT. Because information obtained by the petitioners indicates that most of Garware's U.S. sales are through its affiliated importer in the United States, the petitioners have based U.S. price on constructed export price (CEP). For Garware's CEP prices, the petitioners used prices and offers for sale to unaffiliated purchasers in the United States in April and June of 1998. Because the terms of Garware's U.S. sales were delivered, the petitioners calculated a net U.S. price by subtracting estimated costs for shipment from Garware's factory in India to the port of export using publicly available information. In addition, the petitioners subtracted ocean freight expenses calculated from a Garware shipping document obtained by the petitioners. U.S. import duties were estimated by the petitioners using the HTSUS schedule and then subtracted from the prices. The petitioners also subtracted amounts for U.S. merchandise processing fees and U.S. harbor maintenance fees in accordance with section 772(c)(2)(A) of the Act. Based upon their own experience, the petitioners then subtracted estimated U.S. inland freight costs from the port of importation to customers' delivery locations. Finally, the petitioners calculated a selling expense rate based on an average of the selling costs in the domestic industry and subtracted this amount.

With respect to normal value (NV), the petitioners stated that they believe the volume of Indian home market sales was sufficient to form a basis for NV, pursuant to section 773(a)(1)(C)(ii) of the Act. The petitioners obtained gross unit prices and offers for sale during the period contemporaneous with the U.S. sales and offers for sale for products which are either identical or similar to those sold to the United States. Since the home market prices and offers for sale were ex-factory, the petitioners made no adjustment to these prices. These home market prices were then converted to U.S. dollar prices using the official exchange rate in effect for the month of the comparison U.S. sale.

While the petitioners believe that Garware's home market is viable, they have also made a dumping analysis based on constructed value (CV) in order to show dumping is occurring under either scenario. The petitioners' calculations are for the Garware ERT compound which was sold/offered for sale in the United States. To calculate CV, the petitioners relied on a chemical analysis of Garware's product to determine its composition. To value the components of Garware's product, the petitioners used Indian data, where possible. Where Indian data was not obtainable, the petitioners used their own costs, stating that the prices they pay are equivalent to world-market prices. We adjusted the petitioners' calculation to reflect that products of various dimensions but of identical chemical composition have the same material usage per unit of weight. To value overhead and SG&A, the petitioners used percentages from the *Notice of Final Determination of Sales at Less Than Fair Value: Persulfates from the People's Republic of China*, 62 FR 27222, 27229 (May 19, 1997) (Persulfates). In *Persulfates* the Department derived the overhead and SG&A percentages from the financial statement of an Indian producer of hydrogen peroxide. Because the information in the petition does not indicate that the production of hydrogen peroxide closely resembles that of ERT, we have not used the overhead and SG&A rates from *Persulfates*. Instead, we have relied on publicly available information from the Reserve Bank of India on the chemical industry, in general. To derive a profit rate, the petitioners compared Garware's home market prices to the cost of production of the product sold.

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of ERT from India are being, or are likely to be, sold at less than fair value. Based on a comparison of CEP to home market prices, the petitioners calculated dumping margins range from 49.43 to 66.51 percent. The estimated dumping margins based on a comparison between the CV of Garware's product and CEP range from 28.93 to 43.66 percent.

Allegations and Evidence of Material Injury and Causation

The petition alleges that the U.S. industry producing the domestic like product is being materially injured, and is threatened with material injury, by reason of the imports of the subject merchandise sold at less than NV. The petitioners explained that the industry's injured condition is evident in the declining trends in net operating profits and income, net sales volumes and values, profit to sales ratios, and capacity utilization. The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. The Department assessed the allegations and supporting evidence regarding material injury and causation and determined that these allegations are supported by accurate

[1] *See Algoma Steel Corp. Ltd.*, v. *United States*, 688 F. Supp. 639, 642–44 (CIT 1988); *High Information Content Flat Panel Displays and Display Glass Therefore from Japan: Final Determination; Rescission of Investigation and Partial Dismissal of Petition*, 56 FR 32376, 32380–81 (July 16, 1991).

and adequate evidence and meet the statutory requirements for initiation. *See* Initiation Checklist, dated September 8, 1998 (public document on file in the Central Records Unit of the Department of Commerce, Room B–099).

Allegation of Critical Circumstances

The petitioners have alleged that critical circumstances exist. To support their allegation, the petitioners have provided evidence in the petition of a trend of increasing imports recently and the potential for even greater increases in the near future. The petitioners also provided evidence suggesting the person by whom, or for whose account, ERT is imported knew or should have known that the merchandise was being sold at less than fair value and that there was likely to be material injury as a result. In taking into consideration the foregoing, we find that the petitioners have alleged the elements of critical circumstances and supported it with reasonably available information. We, therefore, will investigate this matter further.

Initiation of Antidumping Investigation

Based upon our examination of the petition, we have found that the petition meets the requirements of section 732 of the Act. Therefore, we are initiating an antidumping duty investigation to determine whether imports of ERT from India are being, or are likely to be, sold in the United States at less than fair value. Unless this deadline is extended, we will make our preliminary determination by January 26, 1999.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of the petition has been provided to the representatives of the government of India. We will attempt to provide a copy of the public version of the petition to the exporter named in the petition.

International Trade Commission Notification

We have notified the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will determine by October 2, 1998, whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury by reason of imports of ERT from India. A negative ITC determination will result in the investigation being terminated; otherwise, this investigation will proceed according to statutory and regulatory time limits.

This notice is published pursuant to sections 732(d) and 777(i) of the Act.

Dated: September 8, 1998.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 98–24750 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–602]

Industrial Phosphoric Acid From Belgium; Extension of Time Limit for Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Extension of time limit for final results of antidumping duty administrative review of industrial phosphoric acid from Belgium.

SUMMARY: The Department of Commerce (''the Department'') is extending the time limit for the final results of the antidumping duty administrative review of the antidumping order on industrial phosphoric acid from Belgium. This review covers 1 producer/exporter of industrial phosphoric acid. The period of review is August 1, 1996 through July 31, 1997.

EFFECTIVE DATE: September 16, 1998.

FOR FURTHER INFORMATION CONTACT: Todd Peterson or Thomas Futtner, AD/CVD Enforcement Group II, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone (202) 482–4195 or 482–3814, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Tariff Act of 1930 (''the Act'') are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are references to the provisions codified at 19 CFR Part 351.101, et seq. (62 FR 27296—May 19, 1997).

Extension of Preliminary Results

The Department initiated this administrative review on September 25, 1997 (62 FR 50292). Under section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit of 365 days. Because of the complexity of an issue in this case, it is not practicable to complete this review within the statutory time limit of 365 days. The Department, therefore, is extending the time limit for the final results of the aforementioned review to October 8, 1998. See memorandum from Maria Harris Tildon to Robert S. LaRussa, which is on file in Room B–099 at the Department's headquarters.

This extension of time limit is in accordance with section 751(a)(3)(A) of the Act and section 351.213(h)(2) of the Department's regulations.

Dated: September 8, 1998.

Maria Harris Tildon,

Acting Deputy Assistant Secretary, AD/CVD Enforcement Group II.

[FR Doc. 98–24747 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–814]

Pure Magnesium From Canada; Notice of Extension of Time Limit for Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit.

SUMMARY: The Department of Commerce is extending the time limit for the final results of the fifth review of the antidumping duty order on pure magnesium from Canada. The period of review is August 1, 1996 through July 31, 1997. This extension is made pursuant to Section 751(a)(3)(A) of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act.

EFFECTIVE DATE: September 16, 1998.

FOR FURTHER INFORMATION CONTACT: Zak Smith, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–0189.

SUPPLEMENTAL INFORMATION: Because it is not practicable to complete this review within the original time limit mandated by section 751(a)(3)(A) of the Tariff Act of 1930, as amended (*i.e.*,

September 9, 1998), the Department of Commerce is extending the time limit for completion of the final results to not later than November 9, 1998. *See* September 4, 1998 Memorandum from Deputy Assistant Secretary for AD/CVD Enforcement Richard W. Moreland to Acting Assistant Secretary for Import Administration Joseph A. Spetrini on file in the public file of the Central Records Unit, B–099 of the Department.

This administrative review and notice are in accordance with sections 751(a)(1) of the Act (19 U.S.C. 1675 (a)(1)) and 19 CFR section 351.213.

Dated: September 4, 1998.

Richard W. Moreland,

Deputy Assistant Secretary for AD/CVD Enforcement.

[FR Doc. 98–24745 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–816]

Notice of Initiation of Countervailing Duty Investigation: Elastic Rubber Tape from India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 16, 1998.

FOR FURTHER INFORMATION CONTACT: Todd Hansen or Javier Barrientos at (202) 482–1276 and (202) 482–4207, respectively, Import Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Initiation of Investigation

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR Part 351 (1998).

The Petition

On August 18, 1998, the Department of Commerce (the Department) received a petition filed in proper form by or on behalf of Fulflex, Inc., Elastomer Technologies Group, Inc. (Elastomer), and RM Engineered Products, Inc. (RM) (collectively referred to hereinafter as ''the petitioners''). Elastomer and RM are both wholly owned subsidiaries of M-Tec Corporation. A supplement to the petition was filed on September 1, 1998.

In accordance with section 702(b)(1) of the Act, the petitioners allege that manufacturers, producers, or exporters of the subject merchandise in India receive countervailable subsidies within the meaning of section 701 of the Act, and that such imports are materially injuring an industry in the United States. The petitioners estimate the countervailing duty rate for Garware to be 50 percent. This figure is based on the findings of the EU in its Imposition of Provisional Countervailing Duty on Imports of Certain Broad Spectrum Antibiotics Originating in India (OJ L 166/17, Commission Regulation (EC) No. 1204/98, June 11, 1998) and the Department's determination in Certain Iron-Metal Castings from India: Preliminary Results of Countervailing Duty Administrative Review (63 FR 37534, July 13, 1998).

The petitioners state that they have standing to file the petition because they are interested parties, as defined under sections 771(9)(C) and (D) of the Act, and they have demonstrated that they are the only producers of ERT in the United States (*see* ''Determination of Industry Support for the Petition'' section below).

Scope of the Investigation

For purposes of this investigation, the product covered is elastic rubber tape. Elastic rubber tape is defined as vulcanized, non-cellular rubber strips, of either natural or synthetic rubber, 0.006 inches to 0.100 inches (0.15 mm to 2.54 mm) in thickness, and ⅛ inches to 1⅝ inches (3 mm to 42 mm) in width. Such product is generally used in swimwear and underwear.

The merchandise subject to this investigation is classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheading 4008.21.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

During our review of the petition, we discussed scope with the petitioners to insure that the scope in the petitions accurately reflects the product for which they are seeking relief. Moreover, as discussed in the preamble to our regulations (62 FR 27323), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments by September 29, 1998. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The period of scope consultations is intended to provide us with ample opportunity to consider all comments and consult with parties prior to the issuance of our preliminary determinations.

Consultations

Pursuant to section 702(b)(4)(A)(ii) of the Act, the Department invited representatives of the Government of India (GOI) for consultations with respect to the petition. On September 1, 1998, the GOI submitted written comments regarding the programs alleged in the petition. Consultations were held on September 4, 1998. See memorandum to the file regarding the consultations with the GOI, dated September 4, 1998 (public document on file in the Central Records Unit of the Department of Commerce, Room B–099).

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether the petition has the requisite industry support, the statute directs the Department to look to producers and workers who account for production of the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition of domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not

render the decision of either agency contrary to the law. [1]

Section 771(10) of the Act defines domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

The domestic like product referred to in the petition is the single domestic like product defined in the ''Scope of Investigation'' section, above. The Department has no basis on the record to find the petition's definition of the domestic like product to be inaccurate. The Department has therefore adopted the domestic like product definition set forth in the petition.

In this case, the Department has determined that the petition and supplemental information contained adequate evidence of sufficient industry support and, therefore, polling is unnecessary. *See* the Initiation Checklist prepared for this case, dated September 8, 1998 (public documents on file in the Central Records Unit of the Department of Commerce, Room B–099). The petitioners established industry support representing 100 percent of total production of the domestic like product.

Additionally, no person who would qualify as an interested party pursuant to sections 771(9)(A)(B)(C)(D)(E) or (F) has expressed opposition on the record to the petition. Therefore, to the best of the Department's knowledge, the producers who support this petition account for 100 percent of the production of the domestic like product produced by the portion of the industry expressing an opinion regarding the petition. Accordingly, the Department determines that this petition is filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

Injury Test

Because India is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) applies to this investigation. Accordingly, the U.S. International Trade Commission (ITC) must determine whether imports of the subject merchandise from India materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petition alleges that the U.S. industry producing the domestic like product is being materially injured, and is threatened with material injury, by reason of the subsidized imports of the subject merchandise from India. The petitioners explain that the industry's injured condition is evident in the declining trends in net operating profits and income, net sales volumes and values, profit to sales ratios, and capacity utilization. The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. The Department assessed the allegations and supporting evidence regarding material injury and causation, and it determined that these allegations are sufficiently supported by accurate and adequate evidence and meet the statutory requirements for initiation (*see* Attachment 2 to the September 8, 1998, Initiation Checklist entitled ''Analysis of Allegations and Evidence of Material Injury and Causation'').

Allegation of Critical Circumstances

The petitioners allege that critical circumstances exist with respect to imports of ERT from India. To support this allegation, the petitioners have provided evidence in the petition of a trend of increasing imports recently and the potential for even greater increases in the near future. The petitioners also have asserted that the alleged subsidies are inconsistent with the Subsidies Agreement, based on the fact that both the Department and the European Union have determined several of the alleged subsidies to be countervailable export or import substitution subsidies in other countervailing duty proceedings. In taking into consideration the foregoing, we find that petitioners have alleged the elements of critical circumstances and supported it with reasonably available information. We, therefore, will investigate this matter further.

Initiation of Countervailing Duty Investigation

Section 702(b) of the Act requires the Department to initiate a countervailing duty proceeding whenever an interested party files a petition, on behalf of an industry, that (1) alleges the elements necessary for an imposition of a duty under section 701(a), and (2) is accompanied by information reasonably available to the petitioners supporting the allegations.

The Department has examined the petition on elastic rubber tape (ERT) from India and found that it complies with the requirements of section 702(b) of the Act. Therefore, in accordance with section 702(b) of the Act, we are initiating a countervailing duty investigation to determine whether manufacturers, producers, or exporters of ERT from India receive subsidies. See the September 8, 1998, Initiation Checklist regarding the initiation of this investigation. We will make our preliminary determination by November 12, 1998, unless this deadline is extended.

We are including in our investigation the following programs alleged in the petition to have provided subsidies to producers and exporters of the subject merchandise in India:

1. Passbook/Duty Entitlement Passbook Schemes.
2. Export Promotion Capital Goods Scheme.
3. Export Processing Zones/Export Oriented Units Programs.
4. Income Tax Exemption Scheme.
5. Pre-Shipment Export Financing.
6. Post-Shipment Export Financing.
7. Import Mechanism (Sale of Import Licenses).
8. Exemption of the Interest Tax on Export Credits.
9. Rediscounting of Export Bills Abroad.
10. Programs Operated by the Small Industries Development Bank of India.
11. Special Imprest Licenses.
12. Market Development Assistance.
13. Special Benefits to Export and Trading Houses and Super Star Trading Houses.
14. Duty Drawback on Excise Taxes.
15. Pre-Shipment Export Financing in Foreign Currency.

We are not including in our investigation the following program alleged to be benefitting producers and exporters of the subject merchandise in India:

Location Grants

The petitioners alleged that Garware may have received grants during the POI for having located its facilities in the ''Maharashtra Industrial Zone.'' The petitioners did not provide any additional information such as the name of a particular program, the government agency administering the program, the eligibility requirements, or the specific manner in which benefits are provided.

We are not including this alleged subsidy in our investigation because the petitioners have not provided sufficient information. While the petitioners have

[1] See *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 642–44 (CIT 1988); *High Information Content Flat Panel Displays and Display Glass Therefor from Japan: Final Determination; Rescission of Investigation and Partial Dismissal of Petition,* 56 FR 32376, 32380–81 (July 16, 1991).

asserted that Garware received government grants due to its location in an industrial zone, they have provided no factual information regarding a specific program under which these alleged grants may have been provided. Furthermore, the petitioners have not provided evidence that companies located in ''industrial zones'' are eligible for certain benefits. (We note that we are including in our investigation Export Processing Zones, Falta Free Trade Zones and Other Free Trade Zones.) Given the lack of information regarding this allegation, we are not including it in our investigation.

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act, copies of the public version of the petition have been provided to the representatives of the Government of India. We will attempt to provide copies of the public version of the petition to all the exporters named in the petition, as provided for under section 351.203(c)(2) of our regulations.

ITC Notification

Pursuant to section 702(d) of the Act, we have notified the ITC of this initiation.

Preliminary Determination by the ITC

The ITC will determine by October 2, 1998, whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, by reason of imports of ERT from India. A negative ITC determination will result in the investigation being terminated; otherwise, the investigation will proceed according to statutory and regulatory time limits.

This notice is published pursuant to sections 702(c) and 777(i) of the Act.

Dated: September 8, 1998.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 98–24749 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Weather Service Modernization and Associated Restructuring

AGENCY: National Weather Service (NWS), NOAA, Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The NWS is publishing proposed certifications for the consolidation, automation, and closure of the Huntsville, Alabama Weather Service Office (WSO) which would be automated at FAA Weather Observation Service Level B and have its services consolidated into the future Birmingham, Alabama Weather Forecast Office (WFO).

In accordance with Pub. L. 102–567, the public will have 60-days in which to comment on these proposed consolidation, automation, and closure certifications.

DATES: Comments are requested by November 16, 1998.

ADDRESSES: Request for copies of the proposed consolidation, automation and closure package should be sent to Tom Beaver, Room 11426, 1325 East-West Highway, Silver Spring, MD 20910, telephone 301–713–0300. All comments should be sent to Tom Beaver at the above address.

FOR FURTHER INFORMATION CONTACT: Tom Beaver at 301–713–0300.

SUPPLEMENTARY INFORMATION: In accordance with section 706 of Pub. L. 102–567, the Secretary of Commerce must certify that this consolidation, automation, and closure will not result in a degradation of service to the affected area of responsibility and must publish the proposed consolidation, automation, and closure certifications in the FR. The documentation supporting these proposed certifications includes the following:

(1) A draft memorandum by the meteorologist-in-charge recommending the certification, the final of which will be endorsed by the Regional Director and the Assistant Administrator of the NWS if appropriate, after consideration of public comments and completion of consultation with the Modernization Transition Committee (the Committee);

(2) A description of local weather characteristics and weather-related concerns which affect the weather services provided within the service area;

(3) A comparison of the services provided within the service area and the services to be provided after such action;

(4) A description of any recent or expected modernization of NWS operation which will enhance services in the service area;

(5) An identification of any area within the affected service area which would not receive coverage (at an elevation of 10,000 feet) by the next generation weather radar network;

(6) Evidence, based upon operational demonstration of modernized NWS operations, which was considered in reaching the conclusion that no degradation in service would result from such action including the WSR–88D Radar Commissioning Report, User Confirmation of Services Report, and the Decommissioning Readiness Report;

(7) Evidence, based upon operational demonstration of modernized NWS operations, which was considered in reaching the conclusion that no degradation in service will result from such action including the ASOS Commissioning Report; series of three letters between NWS and FAA confirming that weather services will continue in full compliance with applicable flight aviation rules after ASOS commissioning; Surface Aviation Observation Transition Checklist documenting transfer of augmentation and backup responsibility from NWS to FAA; successful resolution of ASOS user confirmation of services complaints; and an in-place supplementary data program at the responsible WFO;

(8) Warning and forecast verification statistics for pre-modernized and modernized services which were utilized in determining that services have not been degraded;

(9) An Air Safety Appraisal for offices which are located on an airport; and

(10) A letter appointing the liaison officer.

These proposed certifications do not include any report of the Committee which could be submitted in accordance with sections 706(b)(6) and 707(c) of Pub. L. 102–567. In December 1995 the Committee decided that, in general, they would forego the optional consultation on proposed certifications. Instead, the Committee would just review certifications after the public comment period has closed so their consultation would be with the benefit of public comments that had been submitted.

This notice does not include the complete certification package because it is too voluminous to publish. Copies of the certification package and supporting documentation can be obtained through the contact listed above.

Once all public comments have been received and considered, the NWS will complete consultation with the Committee and determine whether to proceed with the final certification. At the June 25, 1997 MTC meeting the Committee stated that its endorsement of certifications is ''subject to the following qualifications:

(1) The number of trained staff in each modernized field office meets staffing requirements as established by the modernization criteria and documented

in the National Implementation Plan and the Human Resources Plan (WBS 1100). Delays in training or failure to fill required positions will increase the risk of degradation of service;

(2) The availability of operational systems in each modernized field office meets requirements as established by the modernization criteria and documented in the System Commissioning and Support Function Demonstration Plans; and

(3) The operational and administrative infrastructures and technical development needed to support the modernized field offices be maintained as required by the modernization plan.'' These qualifications have been met for the above proposed certifications. If a decision to certify is made, the Secretary of Commerce must publish final certifications in the FR and transmit the certifications to the appropriate Congressional committees prior to consolidating, automating, and closing this office.

Dated: September 11, 1998.

John J. Kelly, Jr.,

Assistant Administrator for Weather Services.

[FR Doc. 98–24798 Filed 9–15–98; 8:45 am]

BILLING CODE 3510–12–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of the Ballistic Missile Defense Advisory Committee

ACTION: Notice.

SUMMARY: The Ballistic Missile Defense Advisory Committee (BMDAC) has been renewed in consonance with the public interest, and in accordance with the provisions of Pub. L. 92–463, the ''Federal Advisory Committee Act.''

The BMDAC provides the Director, Ballistic Missile Defense Organization and the Secretary of Defense with advice and insights into the ballistic missile defense program, and makes recommendations on the program emphasis, schedule and content. The BMDAC assesses all matters relating to acquisition system development, and technology for defense against ballistic missile threat.

The Committee will continue to be composed of 15–20 leaders from government and the private sector who are recognized authorities in defense policy, acquisition and technical areas related to the ballistic missile defense program. Efforts will be made to ensure that there is a fairly balanced membership in terms of the functions to be performed and the interest groups represented.

DATES: August 17, 1998.

FOR FURTHER INFORMATION CONTACT:

Please contact LTC Bailey, Assistant Chief of Staff, on 697–3527.

Dated: September 10, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–24787 Filed 9–15–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Tuition Waiver

On August 13, 1998, the Acting Assistant Secretary of Defense (FMP) signed a memorandum that extends through School year 1998–99, two class tuition waivers in certain DoD Dependent Schools that expired at the end of the SY 1997–98. The August 13 memorandum extends the tuition waiver signed on February 14, 1995, by the Assistant Secretary of Defense (Force Management Policy (ASD(FMP)) waiving tuition on a space-available basis for the enrollment of the class of dependents of active diplomatic, defense attaché, and military liaison personnel from Newly Independent States of the former Soviet Union. The August 13 memorandum also extends the class tuition waiver signed by the ASD(FMP) on June 9, 1995, for the enrollment on a space-available basis, in the SHAPE International School and the Brussels American School of children of diplomatic and defense liaison personnel participating in the Partnership for Peace (PfP) program. The August 13 Memorandum broadens the PfP class waiver to include the dependents of military and diplomatic personnel participating in the PfP program in Naples, Italy; London, United Kingdom; and Brunssum, the Netherlands.

Supplementary Information: Copies of DoD Directive 1342.13, ''Eligibility Requirements for Education of Minor Dependents in Overseas Areas,'' dated July 2, 1982, are available, at cost, from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Questions can be addressed to the Department of Defense Education Activity, Attention: Dr. Jerald E. Bloom, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

Dated: September 9, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–24784 Filed 9–15–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Department of Defense Wage Committee; Notice of Closed Meetings

Pursuant to the provisions of section 10 of Public Law 92–463, the Federal Advisory Committee Act, notice is hereby given that closed meetings of the Department of Defense Wage Committee will be held on October 6, 1998; October 13, 1998; October 20, 1998; and October 27, 1998, at 10:00 a.m. in Room A105, The Nash Building, 1400 Key Boulevard, Rosslyn, Virginia.

Under the provisions of section 10(d) of Public Law 92–463, the Department of Defense has determined that the meetings meet the criteria to close meetings to the public because the matters to be considered are related to internal rules and practices of the Department of Defense and the detailed wage data to be considered were obtained from officials of private establishments with a guarantee that the data will be held in confidence.

However, members of the public who may wish to do so are invited to submit material in writing to the chairman concerning matters believed to be deserving of the Committee's attention.

Additional information concerning the meetings may be obtained by writing to the Chairman, Department of Defense Wage Committee, 4000 Defense Pentagon, Washington, DC 20301–4000.

Dated: September 9, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–24783 Filed 9–15–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Defense Finance and Accounting Service

Privacy Act of 1974; System of Records

AGENCY: Defense Finance and Accounting Service, DoD.

ACTION: Notice of a system of records.

SUMMARY: The Defense Finance and Accounting Service proposes to add a system of records notice to its inventory

of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on October 16, 1998, unless comments are received that would result in a contrary determination.

ADDRESSES: Defense Finance and Accounting Service, 1931 Jefferson Davis Highway, ATTN: DFAS/CEE, Arlington, VA 22240-5291.

FOR FURTHER INFORMATION CONTACT: Ms. Pauline E. Korpanty at (703) 607-3832.

SUPPLEMENTARY INFORMATION: The complete inventory of Defense Finance and Accounting Service record system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act was submitted on August 21, 1998, to the House Committee on Government Reform and Oversight, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (61 FR 6427, February 20, 1996).

Dated: September 9, 1998.

L.M. BYNUM,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

T3020

SYSTEM NAME:

Living Disaster Recovery Planning System (LDRPS).

SYSTEM LOCATION:

Defense Finance and Accounting Service Headquarters, 1931 Jefferson Davis Highway, Arlington, VA 22240–5291.

Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–8000.

Defense Finance and Accounting Service-Indianapolis Center, 8899 East 56th Street, Indianapolis, IN 46249–1460.

Defense Finance and Accounting Service-Columbus Center, 4280 East 5th Avenue, Building 3, Columbus, OH 43218–2317.

Defense Finance and Accounting Service-Cleveland Center, 1240 East 9th Street, Cleveland, OH 44199–2056.

Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All civilian and military individuals employed by the Defense Finance and Accounting Service; may also include civilian and military personnel of the Department of Defense and other Government agencies; may also include family members and other emergency points-of-contact; and contractor organizations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, organization(s), assignment, office and home telephone number(s), grade/rank, military branch of service, position title, job series, disability information, and emergency point-of-contact name and telephone numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; DFAS Regulation 3020.26, Corporate Contingency Plan; and E.O. 9397 (SSN).

PURPOSE(S):

To provide DFAS with a standardized automated contingency planning process. Personal information in the system is used to publish organizational telephone directories/locators, recall personnel to place of duty when required, for use in emergency notification, and to perform relevant functions/requirements/actions consistent with managerial functions during an emergency/disaster.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To Federal, state, or local governments or civic organizations during actual emergencies, exercises, or continuity of operation tests for the purpose of responding to emergency situations.

The 'Blanket Routine Uses' published at the beginning of the DFAS compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on a computer client server at each location.

RETRIEVABILITY:

Retrieved by individual's name, by organization, and by employee ID (which is a combination of individual's first and last name).

SAFEGUARDS:

As a minimum, records are accessed by person(s) responsible for servicing and authorized to use the record system in performance of their official duties who are properly screened and cleared for need-to-know. Access to the system is controlled through User Ids and passwords.

RETENTION AND DISPOSAL:

Records are perpetual because individual records are deleted or added when the file is updated.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Directory, Plans and Management, Defense Finance and Accounting Service Headquarters, 1931 Jefferson Davis Highway, Arlington, VA 22240–5291.

Director of Plans Directorate, Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–8000.

Director of Plans and Management Directorate, Defense Finance and Accounting Service-Indianapolis Center, 8899 East 56th Street, Indianapolis, IN 46249–1460.

Director of Plans and Management Directorate, Defense Finance and Accounting Service-Columbus Center, 4280 East 5th Avenue, Building 3, Columbus, OH 43218–2317.

Director of Plans and Management Directorate, Defense Finance and Accounting Service-Cleveland Center, 1240 East 9th Street, Cleveland, OH 44199–2056.

Director of Plans and Management Office, Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Privacy Act Officer at the appropriate DFAS location.

Individual should furnish full name, current DFAS organization element, current work address, and work telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves in this system of records should address written inquiries to the Privacy Act

Officer at the appropriate DFAS location.

Individual should furnish full name, current DFAS organization element, current work address, and work telephone number.

CONTESTING RECORD PROCEDURES:

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11–R; 32 CFR part 324; or may be obtained from the Privacy Act Officer at any DFAS Center.

RECORD SOURCE CATEGORIES:

Information is obtained from record subject.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 98–24785 Filed 9–15–98; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF DEFENSE

Defense Finance and Accounting Service

Privacy Act of 1974; Notice of Systems of Records

AGENCY: Defense Finance and Accounting Service, DoD.

ACTION: Notice of systems of records.

SUMMARY: The Defense Finance and Accounting Service proposes to add three systems of records notices to its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on October 16, 1998, unless comments are received that would result in a contrary determination.

ADDRESSES: Defense Finance and Accounting Service, 1931 Jefferson Davis Highway, ATTN: DFAS/CEE, Arlington, VA 22240-5291.

FOR FURTHER INFORMATION CONTACT: Ms. Pauline E. Korpanty at (703) 607-3832.

SUPPLEMENTARY INFORMATION: The complete inventory of Defense Finance and Accounting Service record system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act was submitted on August 27, 1998, to the House Committee on Government Reform and Oversight, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (61 FR 6427, February 20, 1996).

Dated: September 9, 1998.

L.M. BYNUM,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

T5015a

SYSTEM NAME:

Military Pay Correction Case Files.

SYSTEM LOCATION:

Defense Finance and Accounting Service-Indianapolis Center, 8899 E. 56th Street, Indianapolis, IN 46249–0001;

Defense Finance and Accounting Service-Cleveland Center, 1240 East Ninth Street, Cleveland, OH 44199–2055;

Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–5000;

Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former military active duty personnel; military active and inactive Reserve and National Guard personnel; retired military personnel; Academy cadets; surviving dependents of military personnel who have applied for waiver of claims arising from erroneous payments of pay and allowances, travel, transportation, and relocation allowances.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name; Social Security Number; grade or rank; date of birth; application; beneficiary information; names and addresses of dependents; cash payment records; check number; financial returns; military pay and allowances vouchers; collection vouchers; travel orders and vouchers; record of travel payments; public vouchers; certificates; pay adjustment authorization; active duty, reserve, and retired military pay records; leave and earnings statements; statement of service; promotion and performance of hazardous duty information; individual pay account records; pay account histories; supplemental wage and tax statement; requests, authorizations, and pay orders for basic allowance for subsistence; leave records; medical bills and receipts; discharge documents; preceding civilian payrolls; preceding civilian earnings, wage, and tax statements; employment history; bills of lading; claims for pay or other entitlements and correspondence; reports of investigation; income tax information; social security tax deductions; income tax returns provided by individuals to support a claim; allotment information (allottee's name, address, and amounts paid); related correspondence about waiver or remission of indebtedness; information about judicial proceedings regarding bankruptcy and Federal Housing Administration, United States Treasury Department, Internal Revenue Service, and General Accounting Office inquiries, copies of court martials and non-judicial punishment; application for correction of records; record of disposition; vouchers and supporting documents that substantiate adjustments to pay accounts; and token payment information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 1552; Pub.L. 89–508, Federal Claims Collection Act of 1966; and Pub.L. 97–365, Debt Collection Act of 1982, as amended; and E.O. 9397 (SSN).

PURPOSE(S):

To determine the proper payment due based on the correction of military records. Correction of military records includes any correction of former civilian entitlements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Internal Revenue Service and the Social Security Administration for the purposes of determining tax liabilities and Social Security entitlements flowing from corrections of military pay and allowances or previous civilian entitlements.

To State unemployment offices for the purposes of instituting collection procedures or other actions against the member if the member was collecting unemployment compensation.

The 'Blanket Routine Uses' published at the beginning of the DFAS compilation of systems of records notices apply to this system.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to 'consumer reporting agencies' as defined in the Fair Credit Reporting Act, 14 U.S.C. 1681a(f) or the Federal Claims Collection Act of 1966, 31 U.S.C. 3701(a)(3). The purpose of the disclosure is to aid in the collection of outstanding debts owed to the Federal Government; typically, to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records.

The disclosure is limited to information necessary to establish the identity of the individual, including name, address, and taxpayer identification number (Social Security Number); the amount, status, and history of the claim; and the agency or program under which the claim arose.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders, computer printouts, and magnetic and microform media.

RETRIEVABILITY:

Filed by name, Social Security Number, taxpayer identification number, or military service number.

SAFEGUARDS:

Records are accessed by the custodian of the record system and by persons responsible for servicing the record system in performance of their official duties. Records are stored in security file containers, cabinets, or computers in guarded buildings.

RETENTION AND DISPOSAL:

Records are destroyed 6 years after the final closing date. Destruction is by shredding, macerating, pulping, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Military Pay Director, Defense Finance and Accounting Service-Indianapolis Center, 8899 E. 56th Street, Indianapolis, IN 46249–0001;

Military Pay Director, Defense Finance and Accounting Service-Cleveland Center, 1240 East Ninth Street, Cleveland, OH 44199–2055;

Military Pay Director, Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–5000;

Military Pay Director, Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Privacy Act Officer at the appropriate DFAS Center.

Individual should furnish full name, Social Security Number, current address, and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Privacy Act Officer at the appropriate DFAS Center.

Individual should furnish full name, Social Security Number, current address, and telephone number.

CONTESTING RECORD PROCEDURES:

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11–R; 32 CFR part 324; or may be obtained from the Privacy Act Officer at any DFAS Center.

RECORD SOURCE CATEGORIES:

Records are obtained from the individual, military finance and accounting offices, other government agencies, previous employers, automated systems interfaces, source documents (such as reports), credit unions, credit bureaus, insurance companies, courts, and financial institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

T5015b

SYSTEM NAME:

Privacy Act Request Files.

SYSTEM LOCATION:

Defense Finance and Accounting Service Headquarters, 1931 Jefferson Davis Highway, Arlington, VA 22240-5291;

Defense Finance and Accounting Service-Indianapolis Center, 8899 E. 56th Street, Indianapolis, IN 46249–0001;

Defense Finance and Accounting Service-Cleveland Center, 1240 East Ninth Street, Cleveland, OH 44199–2055;

Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–5000;

Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001; and

Defense Finance and Accounting Service-Columbus Center, 4280 East 5th Avenue, Building 6, Columbus, OH 43218–2317.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All persons who request access to, information from, or amendment of records about themselves maintained by the Defense Finance and Accounting Service under the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

CATEGORIES OF RECORDS IN THE SYSTEM:

Letters, memoranda, legal opinions, messages, and miscellaneous documents relating to an individual's request for access to, or amendment of, records concerning that person, including letters of denial, appeals, statements of disagreements, and related documents accumulated in processing requests received under the Privacy Act of 1974.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 5 U.S.C. 552a, The Privacy Act of 1974, as amended, as implemented by DFAS Regulation 5400.11–R; and E.O. 9397 (SSN).

PURPOSE(S):

To record, process, and coordinate individual requests for access to, or amendment of personal records, and appeals on denials of requests for access or amendment to personal records.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information from this system may be provided to other Federal, state, and local agencies when it is necessary to coordinate responses or denials.

The 'Blanket Routine Uses' published at the beginning of the DFAS compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders, microfilm, and/or optical disk systems.

RETRIEVABILITY:

Retrieved by name and Social Security Number.

SAFEGUARDS:

As a minimum, records are accessed by person(s) responsible for servicing and authorized to use the record system in performance of their official duties who are properly screened and cleared for need-to-know. Additionally, at some Centers, records are in office buildings protected by guards and controlled by personnel screening and visitor registers.

RETENTION AND DISPOSAL:

Official Privacy Act requests are kept a minimum of 2 years; requests denied but not appealed are destroyed after 5 years; requests for access or amendment and appeals or denial are destroyed 4 years after final action or 3 years after adjudication by the courts, whichever is later; control logs of accounting of disclosures are kept 5 years or in accordance with the approved disposition instructions for the related subject records, whichever is later, then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Privacy Act Officer, Defense Finance and Accounting Service Headquarters, 1931 Jefferson Davis Highway, Arlington, VA 22240–5291;

Privacy Act Officer, Defense Finance and Accounting Service-Indianapolis Center, 8899 E. 56th Street, Indianapolis, IN 46249–0001;

Privacy Act Officer, Defense Finance and Accounting Service-Cleveland Center, 1240 East Ninth Street, Cleveland, OH 44199–2055;

Privacy Act Officer, Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–5000;

Privacy Act Officer, Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001; and

Privacy Act Officer, Defense Finance and Accounting Service-Columbus Center, 4280 East 5th Avenue, Building 6, Columbus, OH 43218–2317.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Privacy Act Office at the appropriate DFAS Center.

Individual should furnish full name, Social Security Number, current address, and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Privacy Act Officer at the appropriate DFAS Center.

Individual should furnish full name, Social Security Number, current address, and telephone number.

CONTESTING RECORD PROCEDURES:

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11–R; 32 CFR part 324; or may be obtained from the Privacy Act Officer at any DFAS Center.

RECORD SOURCE CATEGORIES:

Records are obtained from the individual requester, DFAS organizations, other Department of Defense organizations, and Federal, state, and local governments, as applicable or appropriate, for processing the case.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

T5500a

SYSTEM NAME:

Congressional Inquiry File.

SYSTEM LOCATION:

Primary location: Defense Finance and Accounting Service Headquarters, 1931 Jefferson Davis Highway, Arlington, VA 22240-5291.

Secondary locations: Defense Finance and Accounting Service-Indianapolis Center, 8899 East 56th Street, Indianapolis, IN 46249–0001.

Defense Finance and Accounting Service-Cleveland Center, 1240 East Ninth Street, Cleveland, OH 44199–2055.

Defense Finance and Accounting Service-Denver Center, 6760 East Irvington Place, Denver, CO 80279–5000.

Defense Finance and Accounting Service-Kansas City Center, 1500 East 95th Street, Kansas City, MO 64197–0001.

Defense Finance and Accounting Service-Columbus Center, 4280 East Fifth Avenue, Columbus, OH 43219-1879.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual who contacts a Member of Congress requesting that the Member solicit information from the Defense Finance and Accounting Service (DFAS) on their behalf.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence and related records from and to Members of Congress pertaining to requests for Congressional assistance in resolving problems.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; E.O. 9397 (SSN); DoD Directive 5400.4 and DFAS Regulation 003.

PURPOSE(S):

To maintain a record of Congressional inquiries and the DFAS response.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the DFAS compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper files.

RETRIEVABILITY:

Retrieved by constituent's name and Social Security Number, and Congressmen's name.

SAFEGUARDS:

As a minimum, records are accessed by person(s) responsible for servicing and authorized to use the record system in performance of their official duties who are properly screened and cleared for need-to-know. Additionally, at some Centers, records are in office buildings protected by guards and controlled by personnel screening and visitor registers.

RETENTION AND DISPOSAL:

Records are retained for 1 to 3 years, then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Congressional Liaison Office, Defense Finance and Accounting Service Headquarters, 1931 Jefferson Davis Highway, Arlington, VA 22240–5291.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Chief, Congressional Liaison Office, Defense Finance and Accounting Service, ATTN: Privacy Act Officer at the appropriate DFAS Center.

Individual should furnish full name, Social Security Number, current

address, telephone number and/or other identifying information verifiable from the records.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Chief, Congressional Liaison Office, Defense Finance and Accounting Service, ATTN: Privacy Act Officer at the appropriate DFAS Center.

Individual should furnish full name, Social Security Number, current address, telephone number and/or other identifying information verifiable from the records.

CONTESTING RECORD PROCEDURES:

The DFAS rules for accessing records, for contesting contents and appealing initial agency determinations are published in DFAS Regulation 5400.11–R; 32 CFR part 324; or may be obtained from the Privacy Act Officer at any DFAS Center.

RECORD SOURCE CATEGORIES:

Information is obtained from the individual requester.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 98–24786 Filed 9–15–98; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507 (j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by September 16, 1998.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer: Department of Education, Office of Management and Budget; 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address Werfel—d@a1.eop.gov. Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address Pat__Sherrill@ed.gov, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Deputy Chief Information Officer, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: September 10, 1998.

Hazel Fiers,

Acting Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: Reinstatement.

Title: Case Service Report.

Abstract: As required by Section 13 of the Rehabilitation Act, the data are submitted by State vocational rehabilitation agencies each year. The data contain personal and program-related characteristics, including economic outcomes of persons with disabilities whose case records are closed.

Additional Information: The basic data comprising the Case Service Report system (RSA–911) are mandated by the Rehabilitation Act of 1973, as amended through 1993. The Department of Education will be using the existing format. The Department will propose a new form and accompanying instructions later this year.

Frequency: Annually.

Affected Public: State, local or Tribal Gov't; SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 82.

Burden Hours: 3,690.

[FR Doc. 98–24689 Filed 9–15–98; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board

AGENCY: National Assessment Governing Board; Department of Education.

ACTION: Notice of information collection activity; request for comment.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces a proposed information collection request (ICR) of the National Assessment Governing Board. The information collection is to conduct validity studies in conjunction with the pilot study of the proposed national tests in 4th grade

reading and 8th grade mathematics, in March 1999. Before submitting the ICR to the Office of Management and Budget (OMB), the Governing Board is soliciting comments on the information collection as described below.

DATES: Comments must be submitted on or before November 16, 1998.

ADDRESSES: Submit written comments identified by ''ICR: Voluntary National Test-Pilot Validity Studies'' by mail or in person addressed to Ray Fields, Assistant Director for Policy and Research, National Assessment Governing Board, Suite 825, 800 North Capitol Street, NW., Washington, DC 20002. Comments may be submitted electronically by sending electronic mail (e-mail) to Ray__Fields@ED.GOV. Comments sent by e-mail must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

All written comments will be available for public inspection at the address given above from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Ray Fields, Assistant Director for Policy and Research, National Assessment Governing Board, Suite 825, 800 North Capitol Street, NW., Washington, DC 20002, Telephone: (202) 357–0395, e-mail: Ray__Fields@ED.GOV.

SUPPLEMENTARY INFORMATION:

I. Information Collection Request

The National Assessment Governing Board is seeking comments on the following Information Collection Request (ICR).

Type of Review: New.

Title: Validity Studies of the Voluntary National Tests in 4th Grade Reading and 8th Grade Mathematics.

Affected Entities: Parties affected by this information collection are state, local, Tribal Government or non-public education agencies.

Abstract: Pub. L. 105–78 vests exclusive authority to develop the voluntary national tests in the Governing Board and also prohibits the use of Fiscal Year 1998 funds for pilot testing, field testing, implementation, administration, or distribution of voluntary national tests. If Congress does not prohibit further development of the voluntary national tests after September 30, 1998, the Governing Board intends to begin pilot testing of items, (i.e. test questions) and conduct validity studies of test procedures in March 1999.

Pub. L. 105–78 also requires the Governing Board to make four determinations about the voluntary national tests: (1) The extent to which test items selected for use on the tests are free from racial, cultural, or gender bias, (2) whether the test development process and test items adequately assess student reading and mathematics comprehension in the form most likely to yield accurate student achievement in reading and mathematics, (3) whether the test development process and test items take into account the needs of disadvantaged, limited English proficient, and disabled students, and (4) whether the test development process takes into account how parents, guardians, and students will appropriately be informed about testing content, purposes and uses.

The purpose of the validity studies is to assess procedures for administering the proposed voluntary national tests in reading and mathematics. Since test administration can affect student performance, the validity studies determine if characteristics of test performance, such as non-standard conditions for students with special needs, affect student performance. Three studies are included in this information collection. Since the VNT is designed to be administered in two, 45-minute sessions, the Effect of Break Length between Testing Sessions validity study will examine this impact on examinee test scores and make recommendations for future administrations of the test. The Effects of Calculator Type validity study will investigate how student familiarity with a particular calculator affects test performance. Design specifications for the 8th grade mathematics test call for the use of a calculator in one testing session. The National Assessment Governing Board undertakes this study to inform policy, for proposed future field and operational tests, about whether to issue standard calculators or permit students to take the test with their own calculator. The Effects of Extended Time and Small Group Administration Accommodations validity study investigates non-standard test administration procedures for the inclusion of students with disabilities and students with limited English proficiency in the voluntary national tests. This study considers the testing accommodations of extended time (up to two times the standard administration test length) and small group administration for students with disabilities, students with limited English proficiency (LEP) and comparison groups of non-disabled, non-LEP students. This study will measure the magnitude of the effect of test accommodations on student performance.

Effects of Break Length between Testing Sessions. The specifications for the VNT call for the test to be administered in two-45 minute sessions given on the same day but do not dictate the specific scheduling of these two sessions. As school personnel will administer the operational VNT, it is likely that there will be some variation in test administration procedures at participating schools. We anticipate that most schools will opt for two morning sessions with a short break between, but some schools may have logistical reasons for administering the test in one morning and one afternoon session. Data will be collected from test administrators on the test administration schedule and activities that occurred during testing sessions. This validity study would describe break lengths and activities, investigate their effects on test performance, and would allow AIR to advise NAGB on scheduling options for the VNT field-test and operational administration.

The Effects of Calculator Type validity study will use released NAEP questions for which national statistics are available, rather than test questions for the VNT pilot test, Eighteen 8th grade students would be recruited to participate in a ''think-aloud'' procedure. Students would take one group of mathematics questions using either their own or a standard issue calculator, followed by another group of questions using the opposite calculator. While answering these questions, examinees would respond to interviewer prompts about their thinking processes. Students would also complete a brief questionnaire about their calculator use in schools. Data would be analyzed to determine the ways in which calculator use and familiarity with calculator features affects student performance.

The Effects of Extended Time and Small Group Administration Accommodations validity study will investigate the impact of accommodations on the test performance of special populations; it will be conducted in two parts. In the first part, 900 students at each grade level will be added as an augmentation to the original pilot sample (300 students with disabilities who would take the VNT either unaccommodated or with accommodations that do not require altered test formats (e.g., large print, oral presentation), 300 students with limited English proficiency, and 300 non-disabled, non-LEP students) would either take the VNT under the standard time condition (two 45-minute

sessions) or under an extended time accommodation (two sessions, each up to 90 minutes). Large schools and schools with large numbers of LEP students would be recruited to participate and would be assigned to one of the two conditions. Because of the small number of eligible students with disabilities in a given school, 110 schools (60 for 4th grade reading, 50 for 8th grade mathematics) will be recruited to participate in this study.

For the second part, the accommodations of extended-time and small-group administration would both be considered for a sample of 750 students with disabilities eligible for small-group or extended time testing accommodations at each grade from schools participating in the pilot sample, both from students in classrooms that will be sampled from those schools for pilot study participation and from the students in the remaining classrooms in those schools. Thus, all students will be selected from schools selected to participate in the main pilot test and some of the students selected for participation in this study will also have been selected for inclusion in the main pilot test.

Small group accommodations are often offered to students with disabilities but the manner of the accommodation varies. The small group accommodation could be a ''pull-out'' session in another classroom, or, due to space or staffing restrictions, the small group may be ''embedded'' in a larger setting (such as a library or cafeteria) where other activity is present. This study distinguishes between these two methods of providing small group accommodations for students with disabilities. A subsample of schools that are already participating in the main pilot VNT would be assigned to one of five conditions: (1) Standard time, small group ''pull-out'' administration, (2) extended time, small group ''pull-out'' administration (3) standard time, ''embedded'' small group administration, (4) extended time, ''embedded'' small group administration, (5) standard time, standard (large) group administration. All eligible students with disabilities in the school would then take the VNT under the prescribed condition. A total of 750 students with disabilities would be recruited at each grade level, resulting in 150 students in each of the five conditions mentioned above. Due to the small number of eligible students with disabilities in a given school, it is estimated that 290 schools (4th grade) and 267 schools (8th grade) would be needed to complete the sample size. Parental consent will be sought for all students selected to participate under conditions different from those identified in their IEPs.

All students in both parts of this study who take a test under the extended time would, at the end of the first 45 minutes of a testing session, be asked to switch to a different color pencil. Students in this condition could then answer remaining items or return to skipped items, using the different color pencil, until they have completed the test or until the end of the extended time period. All students (all conditions) would be asked to complete a short questionnaire about the length of the test.

Data from this study would be analyzed to determine which groups benefit from the accommodation of extended time, which method of small group administration maximizes performance for students with disabilities, and how much accommodations affect test performance. Analyses would also be done to determine if the current test administration procedures provide sufficient time for students to take the VNT. Recommendations will be made for providing appropriate accommodations for students with disabilities and students with limited English proficiency on future field tests and operational tests of the VNT.

In order to ensure adequate control and proper identification of the booklets of test items, and conduct necessary analyses of the data that results from the information collection, the following background information will be collected on the cover of the booklets of test questions: student name, date of birth, race/ethnicity, and sex (all to be supplied by the student), and special education status, limited English proficiency status, disadvantaged status, test administration accommodations, and primary language (collected by the test administrator under contract). Although students will write their name on each booklet for identification purposes during the administration of the pilot test, the students' names will be removed from the booklet shortly after the pilot test. Student names will not be included in the database for analysis and will not leave the school building where pilot testing is taking place. Instead, a unique numeric or alphanumeric identifier will be assigned to each booklet for tracking and analysis purposes. No third party notification or public disclosure burden is associated with this collection.

Burden Statement

Effects of Break Length between Sessions: This study will not require any increase in burden for students above that required for the pilot study. School staff burden for this study is approximately 10 minutes per school (672 for reading and 372 for math) or 174 hours total.

Effects of calculator use study: The respondent burden for this study is 40.5 hours, or 2.25 hours for each of the 18 students participating in the Cognitive Laboratory study. This estimate is based on 90 minutes of cognitive think aloud and 45 minutes of test administration procedures by research staff.

Testing accommodations validity study: The annual burden respondent estimate is based on 90 minutes of testing and 30 minutes of test administration activities (e.g., delivering instructions, handing out and collecting booklets, and providing background information as described above) per student, or two hours per student, in the standard time condition. Students who take the test in the extended time condition have up to three and a half hours each: 30 minutes of test administration activities, and up to 180 minutes of testing time, although this may be less if students finish early. Five hundred seventy-three of the students participating in this study will not require any increase in testing burden above that required for the pilot study, 382 will require an increase of 1.5 hours of testing burden, 327 will be new students with a total testing burden of 2 hours, and 218 will be new students with a total testing burden of 3 hours. In addition, there is an additional 6 minutes of burden per each of the 3,300 students to answer questions about the length of the test. Total student burden for the 3,300 students participating in the 4th grade reading test and 8th grade mathematics test is 7,270 hours. School staff burden for this study, for both reading and mathematics tests, is 225 hours. This includes questions about classroom practices to be asked of school staff by test administrators, 5 minutes each for the 2,700 students with disabilities and students with limited English proficiency included in the study. There is no school staff burden for the 600 students without disabilities or limited English proficiency.

Participation in the pilot test and these validity studies is voluntary. State, local, and non-public education agencies are not mandated or required to participate.

Summary

The total number of students involved in the validity studies, above that which has already been requested in the pilot VNT collection, is 3,318 with a total burden of 7310.5 hours. Total school staff burden for these validity studies is 399 hours.

II. Request for Comments

The National Assessment Governing Board solicits comments to:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Governing Board, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Governing Board's estimates of the burden of the proposed collection of information;

(c) Enhance the quality, utility and clarity of the information to be collected;

(d) Minimize the burden of the collection of the information on those who are to respond, including through the use of appropriate automated, mechanical or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

III. Public Record

A record has been established for this action. A public version of this record, including printed, paper versions of electronic comments, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Suite 825, 800 North Capitol Street, NW., Washington, DC 20002. Comments may be submitted electronically by sending electronic mail (e-mail) to Ray__Fields@ED.GOV. Comments sent by email must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this action, as well as public version, as described above will be kept in paper form. Accordingly, the National Assessment Governing Board will transfer all comments received electronically into printer, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the National Assessment Governing Board, Suite 825, 800 North Capitol Street, NW, Washington DC 20002.

List of Subjects

Pilot tests for the voluntary national tests in 4th grade reading and 8th grade mathematics, validity studies, and Information Collection Request.

Dated: September 11, 1998.

Roy Truby,

Executive Director, National Assessment Governing Board.

[FR Doc. 98–24849 Filed 9–15–98; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Bonneville Power Administration

Availability of the Bonneville Purchasing Instructions (BPI)

AGENCY: Bonneville Power Administration (BPA), DOE

ACTION: Notice of document availability.

SUMMARY: Copies of the BPI which establishes the procedures BPA uses in the solicitation, award, and administration of its purchases of goods and services, including construction, and the Bonneville Financial Assistance Instructions (BFAI) which establishes the procedures BPA uses in the solicitation, award, and administration of financial assistance instruments (principally grants and cooperative agreements) are available from BPA for $30 and $15 each, respectively, or available without charge after October 1, 1998 at the Internet address: http://www.bpa.gov/Corporate/GP/GP.htm.

ADDRESSES: Copies of the BPI or BFAI may be obtained by sending a check for the proper amount to the Head of the Contracting Activity, Routing GP, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208–3621.

FOR FURTHER INFORMATION CONTACT: The Manager, Communications, 1–800–622–4519.

SUPPLEMENTARY INFORMATION: BPA was established in 1937 as a Federal Power Marketing Agency in the Pacific Northwest. BPA operations are financed from power revenues as opposed to annual appropriations. Its purchasing operations are conducted under 16 U.S.C. 832 et seq. and related statutes, pursuant to these special authorities, the BPI is promulgated as a statement of purchasing policy and as a body of interpretative regulations governing the conduct of BPA purchasing activities. It is significantly different from the Federal Acquisition Regulation, and reflects BPA's private sector approach to purchasing the goods and services which it requires. The BPI is available on two 3½ inch diskettes in Microsoft's Word for Window's format in addition to the printed version. Please specify which is desired when placing the order. BPA's financial assistance operations are conducted under 16 U.S.C. 832 *et seq.*, and 16 U.S.C. 839 *et seq.* The BFAI express BPA's financial assistance policy. The BFAI also comprise BPA's rules governing implementation of the principles provided in the following OMB circulars:

A–21 Cost principles applicable to grants, contracts, and other agreements within institutions of higher education.

A–87 Cost principles applicable to grants, contracts, and other agreements with State and local governments.

A–102 Uniform administrative requirements for grants in aid to State and local governments, and the common rule.

A–110 Grants and agreements with institutions of higher education, hospitals and other nonprofit organizations.

A–122 Cost principles applicable to grants, contracts, and other agreements with nonprofit organizations.

A–133 Audits of States, Local Governments and Non-Profit Organizations.

BPA's solicitations include notice of applicability and availability of the BPI and the BFAI, as appropriate, for the information of offerors on particular purchases or financial assistance transactions.

Issued in Portland, Oregon, on August 31, 1998.

Steven C. Kallio,

Manager, Corporate Purchasing and Property Management.

[FR Doc. 98–24812 Filed 9–15–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Execution of Agreements to Install Additional Wind Turbines at the Wyoming Windpower Plant

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of Availability of Record of Decision (ROD).

SUMMARY: BPA has decided to execute one or more agreements with SeaWest Corporation, a wind developer, of San Diego, California, to install additional turbines at the Wyoming Windpower Plant in Carbon County, Wyoming. To acquire the additional output from the turbines, BPA may also execute agreements with PacifiCorp, an Oregon corporation, and/or others for

interconnection, wheeling, and shaping services. BPA will market the electrical output of the turbine additions and expects to execute Power Sale Agreements (PSA) with interested customers. This notice announces the availability of the ROD to execute these agreements, relying on the Kenetech/PacifiCorp Windpower Project Environmental Impact Statement (Wind Project EIS) (DOE/EIS–0255 August, 1995). BPA was a cooperating agency, with the Bureau of Land Management (BLM) the lead agency, in preparation of the Wind Project EIS. BPA previously adopted the Wind Project EIS in a July 1997 ROD that was issued to execute a Power Purchase Agreement (PPA) to acquire a 15.32-megawatt (MW) share of nominal project capacity from the Wyoming Windpower Plant. This ROD is tiered to the July 1997 ROD.

ADDRESSES: Copies of this ROD, the July 1997 ROD, and the Wind Project EIS may be obtained by calling BPA's toll-free document request line: 1–800–622–4520.

FOR FURTHER INFORMATION, CONTACT: Kathy Fisher—ECP, Environmental Project Lead, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon, 97208–3621, phone number (503) 230–4375, fax number (503) 230–5699.

Issued in Portland, Oregon, on September 1, 1998.

Jack Robertson,

Acting Administrator and Chief Executive Officer.

[FR Doc. 98–24813 Filed 9–15–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–766–000]

Florida Gas Transmission Company; Notice of Request Under Blanket Authorization

September 11, 1998.

Take notice that on September 4, 1998, Florida Gas Transmission Company (FGT), 1400 Smith Street, Houston, Texas 77002, filed in docket No. CP98–766–000 a request pursuant to Sections 157.205, and 157.212, of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) for authorization to construct, own and operate a new delivery point in Mobile County Company, Alabama to accommodate gas deliveries to Bay Gas Storage Company, Ltd. (Bay Gas) under FGT's blanket certificate issued in Docket No. CP82–553–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

FGT proposes to construct, own and operate the 8-inch tap that will connect to a 1.7 miles 12-inch lateral to be constructed by Bay Gas for delivery into Bay Gas' Meter Station. Bay Gas requested this additional tap into FGT's 36-inch mainline as a backup to an existing delivery lateral constructed in 1995, in the event that the Bay Gas pressure is too high for FGT to make normal deliveries though Bay Gas' facilities to serve Alabama Power Company's and Alabama Electric Company's firm and interruptible volumes, authorized under Docket No. CP98–249. FGT states that Bay Gas shall reimburse it for all construction costs of approximately $67,300 inclusive of tax gross up.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–24827 Filed 9–15–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–755–000]

Transcontinental Gas Pipe Line Corporation; Notice of Application

September 10, 1998.

Take notice that on September 1, 1998, Transcontinental Gas Pipe Line Corporation (Transco), Post Office Box 1396, Houston, Texas 77251, pursuant to Section 7(b) of the Natural Gas Act and Part 157 of the Federal Energy Regulatory Commission's Regulations, filed an application in Docket No. CP98–755–000 for authorization to (1) partially abandon the original certificate provided in Docket No. CP74–33 for a portion of the Rate Schedule WSS service, (2) continue to provide this abandoned portion of the individually certificated service pursuant to Transco's blanket certificate and Part 284 of the Commission's Regulations, and (3) to waive the open season provision of Transco's FERC Gas Tariff to the extent necessary to enable each converting Rate Schedule WSS shipper to retain its existing firm storage upon conversion of its service.

Transco requests that the conversions to Part 284 blanket service and the abandonment of the corresponding portion of the Rate Schedule WSS certificated service be made effective November 1, 1998 coincidentally with the November 1, 1998 proposed effective date of Transco's Section 4 tariff filing establishing the new Rate Schedule WSS-Open Access. Transco further requests the Commission issue its order in the instant docket, concurrently with authorization of the Section 4 filing, by October 1, 1998. Transco also states that it is converting a portion of its Rate Schedule WSS service to a blanket service at the request of Atlanta Gas Light Company, Chesapeake Utilities Corporation—Delaware Division, Chesapeake Utilities Corporation—Maryland Division, Fort Hill Natural Gas Authority, Penn Fuel Gas, Inc., and Southwestern Virginia Gas Company.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 21, 1998, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or to protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participant as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on its designee on this

application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Transco to appear or be represented at the hearing.

David P. Boergers,

Secretary.

[FR Doc. 98–24825 Filed 9–15–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–3835–003, et al.]

DTE-CoEnergy, L.L.C., et al.; Electric Rate and Corporate Regulation Filings

September 9, 1998.

Take notice that the following filings have been made with the Commission:

1. DTE-CoEnergy, L.L.C.

[Docket No. ER97–3835–003]

Take notice that on September 4, 1998, DTE–CoEnergy, L.L.C., tendered for filing its report of transactions for the second calendar quarter of 1998 which ended on June 30, 1998.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

2. PP&L, Inc.

[Docket No. ER98–1099–000]

Take notice on September 3, 1998, PP&L, Inc., (PP&L), tendered for filing a fully executed Service Agreement replacing the partially executed Service Agreement filed on December 16, 1997, between PP&L and Southern Energy Retail Trading and Marketing, Inc.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

3. FPL Energy Power Marketing, Inc.

[Docket No. ER98–3566–000]

Take notice that on September 4, 1998, FPL Energy Power Marketing, Inc. (FPL PM), tendered for filing an amendment to its June 26, 1998, filing in Docket No. ER98–3566–000, to seek an effective date of sixty days from the date of this September 4th filing.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

4. Nevada Power Company

[Docket No. ER98–4337–000]

Take notice that on September 4, 1998, Arizona Public Service Company (APS), tendered for filing APS's Certificate of Concurrence regarding the Marketplace-McCullogh Interconnection Agreement, filed by Nevada Power Company on August 24, 1998.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

5. Kansas City Power & Light Company

[Docket No. ER98–4469–000]

Take notice that on September 3, 1998, Kansas City Power & Light Company (KCPL), tendered for filing Amendments to Agreements for Firm Power Service between KCPL and the Kansas Electric Power Cooperative, Inc., and associated Service Schedules.

KCPL states that the Amendatory Agreements revise the Agreements pursuant to KCPL's Open Season. KCPL request waiver of the Commission's notice requirements.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

6. Washington Water Power Company

[Docket No. ER98–4470–000]

Take notice that on September 3, 1998, Washington Water Power Company (WWP), tendered for filing with the Federal Energy Regulatory Commission, pursuant to 18 CFR Section 35.13, executed Service Agreements under WWP's FERC Electric Tariff First Revised Volume No. 9, with (1) Snohomish County PUD #1, (which replaces unexecuted Service Agreement No. 51, previously filed with the Commission under Docket No. ER97–1252–000, effective December 15, 1996 and with (2) City of Riverside, California.

WWP requests waiver of the prior notice requirement and requests that the Service Agreement with City of Riverside, California be accepted for filing effective August 18, 1998.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

7. UtiliCorp United Inc.

[Docket No. ER98–4472–000]

Take notice that on September 3, 1998, UtiliCorp United Inc. tendered for filing on behalf of its operating division, WestPlains Energy-Kansas, a Service Agreement under its Power Sales Tariff, FERC Electric Tariff Original Volume No. 12, with Illinois Power Company. The Service Agreement provides for the sale of capacity and energy by WestPlains Energy-Kansas to Illinois Power Company pursuant to the tariff.

UtiliCorp also has tendered for filing a Certificate of Concurrence by Illinois Power Company.

UtiliCorp requests waiver of the Commission's regulations to permit the Service Agreement to become effective in accordance with its terms.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

8. UtiliCorp United Inc.

[Docket No. ER98–4473–000]

Take notice that on September 3, 1998, UtiliCorp United Inc. tendered for filing on behalf of its operating division, WestPlains Energy-Colorado, a Service Agreement under its Power Sales Tariff, FERC Electric Tariff Original Volume No. 11, with Illinois Power Company. The Service Agreement provides for the sale of capacity and energy by WestPlains Energy-Colorado to Illinois Power Company pursuant to the tariff.

UtiliCorp also has tendered for filing a Certificate of Concurrence by Illinois Power Company.

UtiliCorp requests waiver of the Commission's regulations to permit the Service Agreement to become effective in accordance with its terms.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

9. PP&L, Inc.

[Docket No. ER98–4474–000]

Take Notice that on September 3, 1998, PP&L, Inc. (formerly known as Pennsylvania Power & Light Company) (PP&L), filed a Service Agreement dated August 28, 1998, with Northern AES Energy, L.L.C. (Northern), under PP&L's Market-Based Rate and Resale of Transmission Rights Tariff, FERC Electric Tariff, Original Volume No. 5. The Service Agreement adds Northern as an eligible customer under the Tariff.

PP&L requests an effective date of September 3, 1998, for the Service Agreement.

PP&L states that copies of this filing have been supplied to Northern and to the Pennsylvania Public Utility Commission.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

10. Niagara Mohawk Power Corporation

[Docket No. ER98–4475–000]

Take notice that on September 3, 1998, Niagara Mohawk Power Corporation (NMPC), tendered for filing with the Federal Energy Regulatory Commission a revision to Schedule A of Rate Schedule No. 204, between Niagara Mohawk Power Corporation and the New York Power Authority. Schedule A is a list of the Municipal & Rural Electric Cooperative Customers of the Power Authority of the State of New York for whom transmission service is provided by Niagara Mohawk Power Corporation pursuant to Rate Schedule No. 204.

NMPC requests an effective date of July 1, 1998. NMPC has requested waiver of the notice requirements for good cause shown.

NMPC has served copies of the filing upon the New York State Public Service Commission and the New York Power Authority.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

11. Illinois Power Company

[Docket No. ER98–4476–000]

Take notice that on September 3, 1998, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing notification that Heartland Energy Services, Inc. (HES), has assigned its rights and obligations under the transmission service agreements between Illinois Power and HES to Cargill-Alliant, L.L.C. (Cargill). HES has represented to Illinois Power that this assignment was effective as of January 28, 1998.

Copies of this filing were served upon HES, as well as on Cargill and the Illinois Commerce Commission.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

12. Tucson Electric Power Company

[Docket No. ER98–4477–000]

Take notice that on September 3, 1998, Tucson Electric Power Company (TEP), tendered for filing one (1) non-firm umbrella transmission service agreement pursuant to Part II of TEP's Open Access Transmission Tariff, which was filed in Docket No. OA96–140–000.

TEP entered into a umbrella Service Agreement for Non-Firm Point-to-Point Transmission Service with El Paso Energy Marketing Company dated September 3, 1998. Service under this agreement commenced August 4, 1998.

Comment date: September 23, 1998, in accordance with Standard Paragraph E at the end of this notice.

13. Cinergy Services, Inc.

[Docket No. ER98–4478–000]

Take notice that on September 4, 1998, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Power Open Access Transmission Tariff entered into between Cinergy and El Paso Energy Marketing Company (El Paso) and an index of customers.

Cinergy and El Paso are requesting an effective date of August 8, 1998.

Cinergy is serving a copy of this filing on El Paso Energy Marketing Company, the Texas Public Utility Commission, the Public Utilities Commission of Ohio, the Kentucky Public Service Commission, and the Indiana Utility Regulatory Commission.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

14. Deseret Generation & Transmission Co-operative

[Docket No. ER98–4479–000]

Take notice that on September 4, 1998, Deseret Generation & Transmission Co-operative (Deseret), tendered for filing an executed umbrella non-firm point-to-point service agreement with New Energy Ventures, L.L.C., under its open access transmission tariff. Deseret's open access transmission tariff is currently on file with the Commission in Docket No. OA97–487–000.

Copies have been served upon New Energy Ventures, L.L.C.

Deseret requests a waiver of the Commission's notice requirements for an effective date of September 4, 1998.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

15. Southwest Power Pool

[ER98–4480–000]

Take notice that on September 4, 1998, Southwest Power Pool (SPP), tendered for filing two executed service agreements with The Energy Authority (EA), for short-term firm point-to-point transmission service and non-firm point-to-point firm transmission service under the SPP Open Access Transmission Tariff.

Effective date for each of these agreements is August 13, 1998.

Southwest Power Pool requests a waiver of the Commission's 60-day requirements set forth at 19 CFR 35.3.

Copies of this filing were served upon EA.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

16. Great Bay Power Corporation

[Docket No. ER98–4481–000]

Take notice that on September 3, 1998, Great Bay Power Corporation (Great Bay), tendered for filing a service agreement between Columbia Energy Power Marketing Corporation and Great Bay for service under Great Bay's revised Tariff for Short Term Sales. This Tariff was accepted for filing by the Commission on July 24, 1998, in Docket No. ER98–3470–000.

The service agreement is proposed to be effective August 28, 1998.

Comment date: September 24, 1998, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection.

David P. Boergers,

Secretary.

[FR Doc. 98–24762 Filed 9–15–98; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–774–000, et al.]

CNG Transmission Corporation; Texas Eastern Transmission Corporation; Notice of Availability of the Environmental Assessment for the Proposed CNG Transmission Corporation Market Area Storage Project

September 11, 1998.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) on both the natural gas storage field and

pipeline facilities proposed by CNG Transmission Corporation (CNG) and Texas Eastern Transmission Corporation (Texas Eastern) in the above-referenced docket.

The purpose of the proposed facilities would be to provide CNG and Texas Eastern the capability to expand the capacity of the jointly-owned storage facilities to allow for the storage of an additional 10 billion cubic feet (Bcf) of natural gas at the Oakford Storage Field and 12,000 horsepower (hp) of compression at the Oakford Compressor Station in Westmoreland County, Pennsylvania. Also, the proposed facilities would add about 200 million cubic feet per day (MMcf/d) of injection capability and about 393 MMcf/d of additional end-of-January withdrawal capability at the Oakford Storage Field.

CNG would also increase the deliverability of the Greenlick Storage Complex in Potter County, Pennsylvania and increase the working gas capacity of the Fink-Kennedy/Los Creek Storage Complex in Harrison and Lewis Counties, West Virginia.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

Specifically, the EA assesses the potential environmental effects of the construction and operation of CNG and Texas Eastern's proposed modifications to their gas storage and related pipeline facilities in the Oakford Storage Field, including:

- 12,000 horsepower (hp) of additional electric motor-driven compression and related piping and appurtenant facilities at the existing Oakford Compressor Station in Westmoreland County, Pennsylvania;
- About 6 miles of new and replacement storage field well lines of various diameters and lengths. These would consist of:

a. 670 feet of existing 6-inch-diameter well line (JP–266) with a new 12-inch-diameter well line;

b. 5,622 feet of existing 12-inch well line (JP–260) with a new 16-inch-diameter well line;

c. 2,545 feet of existing 6-inch-diameter well line (JP–276) with a new 10-inch-diameter well line;

d. 3,734 feet and 684 feet of existing 6-inch-diameter well lines (JP–204, JP–288) with a new 8-inch-diameter well line;

e. 3,623 feet and 2,228 feet of two existing 8-inch-diameter well lines (JP–182, JP–231) with a new 12-inch-diameter well lines;

f. 822 feet and 50 feet of two existing 6-inch-diameter well lines (JP–432, JP–458) with a new 10-inch-diameter well line; and

g. 4,400 feet of new 24-inch-diameter pipeline (JP–302); and

h. 5,016 feet of new 16-inch-diameter pipeline (JP–303).

- A Gate Valve Junction JP–260/JP–302 and pig receiver/launcher;
- A Gate Valve Junction JP–302/JP–303;
- Two aboveground Gate Valves on pipeline JP–231;
- Various valves, piping, filter separators, buildings, a launcher/receiver, and appurtenant facilities at the Oakford Compressor Station;
- Replacement of dehydration facilities at the Oakford Compressor Station with a new dry desiccant dehydration system that would increase the processing capability by 400 MMcf/d (from 800 MMcf/d to 1,200 MMcf/d); and
- 325 feet of 10-inch-diameter suction line at the Lincoln Heights Compressor Station in Westmoreland County, Pennsylvania replacing an 8-inch-diameter pipeline and related aboveground facilities.

CNG would also increase the deliverability of its Greenlick Compressor Station in Potter County, Pennsylvania from 912 MMcf/d to 1,062 MMcf/d, and increase of 150 MMcf/d. This increase would be achieved by modifying the existing dehydration system and some of the crossover heaters, separators, valves, and other existing facilities.

Further, CNG requests authorization to convert 2.56 billion cubic feet (Bcf) of existing base gas capacity to working gas capacity of Fink-Kennedy/Lost Creek Storage Complex. This conversion would allow CNG to provide additional storage capacity without additional facilities.

Nonjurisdictional Facilities

A nonjurisdictional 138 kilovolt (KV) electric substation would be installed at the Oakford Compressor Station by Allegheny Power Company. The substation would be constructed on a 0.75 acre site on compressor station property along the south side and outside of the existing fence line. It would consist of a 138 KV transformer, poles, breakers, and a 30-foot-long access road all within the existing compressor station facility. In addition, about 1.7 miles of 138 KV electric transmission line would be constructed to the substation by Allegheny Power Company. This facility is analyzed in the EA.

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street, NE., Room 2A, Washington, DC 20426 (202) 208–1371.

Copies of the EA have been mailed to Federal, state and local agencies, public interest groups, interested individuals, newspapers, and parties to this proceeding.

Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments before the date specified below. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send *two* copies of your comments to: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426;
- Label *one* of those copies for the attention of the Environmental Review and Compliance Branch II, PR–11.2;
- Reference Docket No. CP97–774–000; and
- Mail your comments so that they will be received in Washington, DC on or before October 13, 1998.

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).

The date for filing timely motions to intervene in this proceeding has passed. Therefore, parties now seeking to file late interventions must show good cause, as required by section 385.214(b)(3), why this time limitation should be waived. Environmental issues have been viewed as good cause for late intervention. You do not need intervenor status to have your comments considered.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–24828 Filed 9–15–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Filed With the Commission

September 11, 1998.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. Type of Application: Amendment of License to Authorize the City of Hot Springs, Arkansas, (City) to Construct and Operate a New Water Intake with a Capacity to Withdraw 20 Million Gallons Per Day (MGD) From Lake Hamilton. The Proposed Facility would Replace an Existing Intake Constructed in 1966, which Currently Withdraws 12 MGD. The City Currently is Expanding its Existing Ouachita Water Treatment Facilities at Lake Hamilton to Accommodate an Increasing Local Demand for Municipal Water.

b. Project No.: 271–053.

c. Date Filed: September 1, 1998.

d. Applicant: Entergy Arkansas, Inc.

e. Name of Project: Carpenter-Remmel Hydroelectric Project.

f. Location: Garland and Hot Springs Counties, Arkansas.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant Contact: Mr. Bobby Pharr, Entergy Fossil Operations, Lake Catherine/Hydro/ERS, P.O. Box 218, Jones Mill, AR 72105, (501) 620–5674.

i. FERC Contact: Jim Haimes, (202) 219–2780.

j. Comment Date: October 9, 1998.

k. Description of Project: The licensee is requesting the Commission's authorization to permit the City of Hot Springs, Arkansas to construct and operate a new 20 MGD water intake on Lake Hamilton. The proposed facility would replace the City's existing water intake, which currently withdraws up to 12 MGD from Lake Hamilton.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–24826 Filed 9–15–98; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6161–7]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Evaluation of Jobs Through Recycling Grant Projects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Evaluation of Jobs Through Recycling Grant Projects, ICR Number 1865.01. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before October 16, 1998.

FOR FURTHER INFORMATION OR A COPY: Contact Sandy Farmer at EPA by phone at (202) 260–2740, by email at farmer.sandy@epamail.epa.gov, or download off the Internet at http://www.epa.gov/icr and refer to EPA ICR No. 1865.01. Alternatively, download off the Jobs Through Recycling Web site at http://www.epa.gov/jtr/seconds/program/program.htm.

SUPPLEMENTARY INFORMATION:

Title: Evaluation of Jobs Through Recycling Grant Projects, ICR Number 1865.01. This is a new collection.

Abstract: EPA launched the Jobs Through Recycling (JTR) initiative in 1994 to help facilitate the growth of the recycling industry and thereby increase the environmental and economic benefits created by recycling. The industry includes businesses involved in collecting, processing, manufacturing, and selling products made from recovered materials. With JTR, EPA intended to help state and tribal agencies build a support infrastructure of economic development activities which create jobs, increase capital invested in the recycling industry, create new recycling capacity, and increase the amount of secondary materials actually used.

To assess the success of the JTR grant projects, EPA designed a methodology to evaluate the results, accomplishments, and lessons learned from each JTR grant. The first step in the methodology is to review grant workplans, progress and final reports, and grant products. The second step is to interview the grantees as well as one project partner and one business assisted by each grantee. To facilitate the evaluation, EPA developed an interview guide with a standard set of questions for grantees, project partners, and assisted businesses. The interview guide will enable EPA to collect both qualitative and quantitative information on the accomplishments of the JTR grantees through either phone or onsite interviews. Grantees, for example, are asked to describe the lessons learned and challenges overcome in implementing and managing their projects as well as the results, such as the number of jobs created, amount of capital invested, volume of new capacity created, and volume of secondary materials actually used. EPA pilot tested the evaluation process and the discussion guide with six 1994 JTR grants. All participation in JTR project evaluation interviews is voluntary.

The purpose of the ICR is to allow EPA to continue its evaluation of JTR grant projects by measuring the success of the remaining 1994 grant projects as well as the grants awarded in 1995, 1996, and 1997. The information compiled during these interviews will be disseminated to current and future program participants as well as other recycling market development professionals, so that others can replicate project successes and avoid past mistakes. In addition, EPA will use the information gathered to help identify opportunities to improve the overall JTR program and ensure its continued growth and success. Finally, the evaluation will assist EPA in complying with the Government Performance and Results Act of 1993 (GPRA), by measuring progress towards the goals and objectives detailed in the EPA Strategic Plan.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The **Federal Register** Notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on 6/2/98 (63 FR 29988); no comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 6 hours per response from JTR grantees and 2.25 hours per response from project partners and assisted businesses. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Entities potentially affected by this action are JTR grantees, which include state, multistate, and tribal organizations that have received grant funding through JTR. Also affected are project partners (including state and local agencies) and selected businesses assisted by JTR grantees.

Estimated Number of Respondents: 35.

Frequency of Response: One-time only.

Estimated Total Annual Hour Burden: 122.5 hours.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 1865.01 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OP Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460
and
Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA 725 17th Street, NW, Washington, DC 20503

Dated: September 9, 1998.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 98–24838 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6161–3]

Texas; Full Program Adequacy Determination of State Municipal Solid Waste Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative determination of full program adequacy for the State of Texas.

SUMMARY: Section 4005(c)(1)(B) of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984, requires States to develop and implement permit programs to ensure that municipal solid waste landfills (MSWLFs) which may receive household hazardous waste or conditionally exempt small quantity generator waste, comply with the revised Federal MSWLF Criteria (40 CFR part 258). Section 4005(c)(1)(C)of RCRA requires the (EPA) to determine whether States have ''adequate'' permit programs for MSWLFs, but does not mandate issuance of a rule for such determinations.

Texas applied for a determination of adequacy under section 4005 of RCRA. The EPA reviewed Texas' application and made a tentative determination subject to public review and comment, that Texas' MSWLF permit program is adequate to ensure compliance with the revised MSWLF criteria.

DATES: All comments on Texas' application for full determination of adequacy must be received by the close of business on October 16, 1998.

ADDRESSES: Copies of Texas' application for adequacy determination are available for inspection and copying from 8:30 a.m. to 4 p.m. at the following addresses: Texas Natural Resource Conservation Commission File Room, Room 1301, Building F, 12100 Park 35 Circle (Yager Lane Exit, IH 35 North), Austin, Texas (512) 239–0900; EPA Region 6 Library, 1445 Ross Avenue, Dallas, Texas Attn.: Willie Kelley, (214) 665–6760, or Shari McAllister (214) 665–6424. Written comments should be sent to EPA Region 6, Attn. Willie Kelley (6PD–U) 1445 Ross Avenue Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Sherry Fuerst, UST/Solid Waste Section (6PD–U), EPA Region 6, 1445 Ross Ave, Dallas, Texas 75202–2733, phone 214/665–6454.

A. Background

On October 9, 1991, EPA promulgated revised criteria for MSWLFs (40 CFR part 258). Subtitle D of RCRA, as amended by the HSWA of 1984, requires States to develop permitting programs to ensure that facilities comply with the Federal criteria in 40 CFR part 258. Subtitle D also requires, in section 4005, that EPA determine the adequacy of State municipal solid waste landfill permit programs to ensure that facilities comply with the revised Federal criteria at 40 CFR part 258. To fulfill this requirement, the Agency has proposed a State Implementation Rule (SIR). On January 26, 1996, EPA proposed SIR (61 FR 2584) that will provide procedures by which EPA will approve, partially approve, or disapprove State landfill permit programs. The Agency intends to approve adequate State MSWLF permit programs as applications are submitted. Thus, these approvals are not dependent on final promulgation of the SIR. Prior to promulgation of the SIR, adequacy determinations will be made based on the statutory authorities and requirements. In addition, States may use the draft SIR as an aid in interpreting these requirements. The Agency believes that early approvals have an important benefit. Approved State permit programs provide interaction between the State and the

owner/operator regarding site-specific permit conditions. Only those owners/operators located in States with approved permit programs can use the site-specific flexibility provided by part 258 to the extent the State permit program allows such flexibility. The EPA notes that regardless of the approval status of a State and the permit status of any facility, the Federal criteria will apply to all permitted and unpermitted MSWLFs.

The EPA interprets the requirements for States to develop ''adequate'' programs for permits or other forms of prior approval to impose several minimum requirements. First, each State must have enforceable standards for new and existing MSWLFs that are technically comparable to EPA's revised MSWLF criteria. Next, the State must have the authority to issue a permit or other notice of prior approval to all new and existing MSWLFs in its jurisdiction. The State also must provide for public participation in permit issuance and enforcement as required in section 7004(b) of RCRA. Finally, EPA believes that the State must show it has sufficient compliance monitoring and enforcement authorities to take specific action against any owner or operator that fails to comply with an approved MSWLF program.

The EPA Regions will determine whether a State has submitted an ''adequate'' program based on the interpretation outlined above. The EPA has provided specific criteria for this evaluation in the proposed SIR. The EPA expects States to meet all of these requirements for all elements of an MSWLF program before it gives full approval to an MSWLF program.

On September 27, 1993, the EPA Administrator signed the final rule extending the effective date of the landfill criteria for certain classifications of landfills (proposed rule 58 FR 40568, July 28, 1993). Thus, for certain small landfills that fit the small landfill exemption as defined in 40 CFR 258.1(f), the Federal criteria were effective on October 9, 1995, rather than on October 9, 1993. The final rule on the effective date extension was published in the **Federal Register** October 1, 1993 (58 FR 51536).

On August 10, 1995, the EPA published a proposed rule to solicit comments on a two-year delay, until October 9, 1997, of the general compliance date of the MSWLF criteria for qualifying small MSWLFs (60 FR 40799). This allowed EPA time to finalize the proposed alternatives. The final rule on the delay of the compliance date was published in the **Federal Register** on October 6, 1995 (60 FR 52337).

B. State of Texas

On September 23, 1997, Texas submitted an application for a full adequacy determination for the State's MSWLF permit program. The EPA has reviewed Texas' application and has tentatively determined that all portions of Texas' subtitle D MSWLF program will ensure compliance with the revised Federal criteria. On December 17, 1993, EPA published a final determination of partial program adequacy for Texas' program. Further background on the final determination of partial program adequacy appears in 58 FR 65986 (December 17, 1993) and in 58 FR 44821 (August 25, 1993). In those actions, EPA approved all portions of the State's MSWLF permit program except Texas' regulations exempting certain small landfills in arid regions from ground water monitoring requirements. On May 7, 1993 the U.S. Court of Appeals for the District of Columbia Circuit Court (*Sierra Club* v. *EPA*, 992F.2d 337 D.C. Cir. 1993) directed EPA to eliminate an exemption from ground water monitoring for small landfills in arid and remote locations (40 CFR 258.1 (f)(1)).

In effect, the court held that ''* * * the Agency must revise its final rule to require groundwater monitoring, as necessary to detect contamination, at all landfills. While such factors as size, location and climate may affect the extent or kind of monitoring necessary to detect contamination at a specific facility, they can not justify exemption from the statutory monitoring requirement.'' Thus, the Court vacated the small landfill exemption as it pertains to ground water monitoring, directing the Agency to ''* * * revise its rule to require groundwater monitoring at all landfills.'' For that reason, EPA directed Texas to remove the exemption for certain small landfills in arid regions from ground water monitoring. However, with EPA's concurrence, Texas deferred repealing the exemption until EPA adopted a new standard.

On March 26, 1996, the Land Disposal Program Flexibility Act of 1996 was passed (Pub. L. 104–119, March 26, 1996) which provides explicit authority for the ground water monitoring exemption, whereupon EPA reestablished the ground water monitoring exemption (61 FR 50410, September 25, 1996) that had been vacated by the Court. Thereafter, Texas applied for a determination of full program adequacy, since it had retained the ground water monitoring exemption in its rules and was now in conformity with the revised Federal criteria.

The EPA has reviewed Texas' application and has tentatively determined that all portions of the State's application are consistent with the revised Federal criteria. In its application, Texas demonstrated that the State's permit program adequately meets the location restrictions, operating criteria, design criteria, groundwater monitoring and corrective action requirements, closure and post-closure care requirements, and financial assurance criteria in the revised Federal criteria. In addition, the State of Texas also demonstrated that its MSWLF permit program contains specific provisions for public participation, compliance monitoring, and enforcement.

The public may submit written comments on EPA's tentative determination until October 16, 1998. Copies of Texas' application are available for inspection and copying at the locations indicated in the **ADDRESSES** section of this document. The EPA will consider all public comments on its tentative determination that where received during the public comment period. Issues raised by those comments may be the basis for a determination of inadequacy for Texas' program. The EPA's final determination notice will include a summary of the reasons for the final determination and a response to all major comments.

Texas does not claim jurisdiction over Indian lands.

Section 4005(a) of RCRA provides that citizens may use the citizen suit provisions of section 7002 of RCRA to enforce the Federal MSWLF criteria in 40 CFR part 258 independent of any state enforcement program. As EPA explained in the preamble to the MSWLF criteria, EPA expects that any owner or operator complying with provisions in a State program approved by EPA to be in compliance with the Federal criteria. See 56 FR 50978, 50995 (October 9, 1991).

Children's Health Protection: Under Executive Order (E.O.) 13045, for all significant regulatory actions as defined by E.O. 12866, EPA must provide an evaluation of the environmental health or safety effect of a proposed rule on children and an explanation of why the proposed rule is preferable to other potentially effective and reasonably feasible alternatives considered by EPA. This is not a significant regulatory action and is exempt from EO 13045.

Compliance With Executive Order 12866: The office of Management and Budget has exempted this rule from the

requirements of section 3 of Executive Order 12291.

Unfunded Mandates Reform Act: Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the EPA must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector of $100 million or more in any one year.

Today's document contains no Federal mandates (under the regulatory provisions of Title of the UMRA) for State, local, or tribal governments or the private sector. Today's document would merely acknowledge the adequacy of a portion of an existing State program. The EPA has determined that this document would not contain any Federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate or the private sector in any one year. Therefore, today's document is not subject to the requirements of section 202 of the UMRA.

Certification Under the Regulatory Flexibility Act: Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant economic impact on a substantial number of small entities. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

Authority: This notice is issued under the authority of section 4005 of the Solid Waste Disposal Act as amended; 42 U.S.C. 6946.

Dated: August 26, 1998.

Jerry Clifford,

Deputy Regional Administrator, Region 6.

[FR Doc. 98–24738 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30443A; FRL–6029–2]

LidoChem Inc.; Approval of a Pesticide Product Registration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval an application to register the pesticide product eKsPunge, containing an active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: Rita Kumar, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location/telephone number and e-mail address: Rm. 902W5, CM #2, 1921 Jefferson Davis Hwy, Arlington, VA, 703–308–8291; e-mail: kumar.rita@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the **Federal Register**-Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

EPA issued a notice, published in the **Federal Register** of December 9, 1997 (62 FR 64831) (FRL–5756–3), which announced that LidoChem Inc., 20 Village Court, Hazlet, NJ 07730, had submitted an application to register the pesticide product eKsPunge (EPA File Symbol 70644–R), containing the new active ingredient monopotassium phosphate (KH_2PO_4) at 100%, an active ingredient not included in any previously registered product.

The active ingredient for the registered product was amended to read ''Potassium Dihydrogen Phosphate'' commonly known as monopotassium phosphate.

The application was approved on August 12, 1998, as eKsPunge for the control of powdery mildew on apples, cherries, cucumbers, grapes, mangoes, melons, nectarines, peaches, peppers, plums, summer/winter squash, tomatoes, watermelons, and roses (EPA Registration Number 70644–1).

The Agency has considered all required data on risks associated with the proposed use of potassium dihydrogen phosphate, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the pesticide and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health safety determinations which show that use of potassium dihydrogen phosphate when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

More detailed information on this registration is contained in an EPA Pesticide Fact Sheet on potassium dihydrogen phosphate.

A copy of the fact sheet, which provides a summary description of the pesticides, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, D.C. 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: September 4, 1998.

Kathleen D. Knox,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 98–24842 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–830; FRL 6025–8]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticidepetitions proposing the establishment of regulations for residues of certain

pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–830, must be received on or before October 16, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Beth Edwards, ...	Rm. 216, CM #2, 703–305–5400; e-mail: edwards.beth@epamail.epa.gov.	1921 Jefferson Davis Hwy., Arlington, VA
Treva Alston, ...	Rm. 707B, CM #2, 703–308–8373; e-mail: alston.treva@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number PF–830 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF–830 and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 2, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim with minor, non-substantive editorial changes. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Dow AgroSciences

PP 8F5002

EPA has received a pesticide petition (PP 8F5002) from Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46254 proposing pursuant to section 408(d) of the (FF DCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the insecticide spinosad in or on the raw agricultural commodities corn grain including field, sweet (K+CWHR), and pop at 0.02 part per million (ppm); forage, fodder, straw, and hay of cereal grains at 1.0 ppm; legume vegetables (succulent including soybeans) at 0.3 ppm; cucurbits at 0.3 ppm; sorghum grain at 1.0 ppm; sorghum aspirated grain fractions at 3.0 ppm; stone fruit at 0.2 ppm; and wheat grain at 0.02 ppm. Because of the amount of spinosad residue found in corn, sorghum, and wheat products used in animal feeds as well as those commodities with existing residue tolerances that are potentially used in animal rations, the following increases in livestock residue tolerances are being proposed: livestock, meat residue tolerance of 0.1 ppm; livestock, meat byproduct residue tolerance of 0.4 ppm; livestock, fat residue tolerance of 1.5 ppm; a milk residue tolerance of 0.1 ppm; a milk fat residue tolerance of 1.5 ppm. In addition, the following poultry residue tolerances are being proposed: poultry, fat at 0.2 ppm; poultry, meat and meat byproducts at 0.02 ppm; and eggs at 0.02 ppm. An adequate analytical method is available for enforcement purposes. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of spinosad in plants (apples, cabbage, cotton, tomato, and turnip) and animals

(goats and poultry) is adequately understood for the purposes of these tolerances. A rotational crop study showed no carryover of measurable spinosad related residues in representative test crops.

2. *Analytical method*. There is a practical method (immunoassay) for detecting 0.005 ppm and measuring 0.01 ppm levels of spinosad in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set for these tolerances. The method has had a successful method tryout in the EPA's laboratories.

3. *Magnitude of residues*. Magnitude of residue studies were conducted for stone fruit (7 sites for cherries, 6 sites for peaches, 4 sites for plums, and 2 sites for prunes); cucurbits (6 sites for cucumbers, 6 sites for muskmelons, and 3 sites for summer squash); sweet corn (12 sites); field corn (5 sites at 5 x label rate); legume vegetables (11 sites for snap beans, 7 sites for snow peas, and 7 sites at 5 x label rate for soybeans); sorghum (9 sites); and wheat (6 sites at 5 x label rate). Residues found in these studies ranged from ND to 0.14 ppm on stone fruit; ND to 0.19 ppm in cucurbits; ND for field corn grain and sweet corn (K=CWHR); 0.09 to 0.57 ppm for corn forage; 0.03 to 0.82 ppm for corn fodder; ND to 0.23 ppm for legume vegetables; 0.03 to 0.68 ppm for sorghum grain; 0.06 to 0.18 ppm for sorghum forage; 0.06 to 0.29 ppm for sorghum fodder; 2.02 ppm for sorghum aspirated grain fractions; ND to 0.09 ppm for wheat grain; ND to 0.07 ppm for wheat forage; 0.01 to 0.20 ppm for wheat hay; and 0.01 to 0.73 ppm for wheat straw.

B. Toxicological Profile

1. *Acute toxicity*. Spinosad has low-acute toxicity. The rat oral LD_{50} is 3,738 milligram/kilogram (mg/kg) for males and > 5,000 mg/kg for females, whereas the mouse oral LD_{50} is > 5,000 mg/kg. The rabbit dermal LD_{50} is > 5,000 mg/kg and the rat inhalation LC_{50} is > 5.18 mg/1 air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicty*. Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hepatocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been conducted with spinosad. These studies show a lack of genotoxicity.

3. *Reproductive and developmental toxicity*. Spinosad caused decreased body weights in maternal rats given 200 mg/kg/day by gavage (highest dose tested). This was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The no-observed-effect levels (NOELs) for maternal and fetal toxicity in rats were 50 and 200 mg/kg/day, respectively. A teratology study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day (highest dose tested). Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOELs for maternal and fetal toxicity in rabbits were 10 and 50 mg/kg/day, respectively. In a two-generation reproduction study in rats, parental toxicity was observed in both males and females given 100 mg/kg/day (highest dose tested). Perinatal effects (decreased litter size and pup weight) at 100 mg/kg/day were attributed to maternal toxicity. The NOEL for maternal and pup effects was 10 mg/kg/day.

4. *Subchronic toxicity*. Spinosad was evaluated in 13-week dietary studies and showed NOELs/no-observed-adverse-effect levels (NOAELs) of 4.89 and 5.38 mg/kg/day, respectively in male and female dogs; 6 and 8 mg/kg/day, respectively in male and female mice; and 33.9 and 38.8 mg/kg/day, respectively in male and female rats. No dermal irritation or systemic toxicity occurred in a 21–day repeated dose dermal toxicity study in rabbits given 1,000 mg/kg/day.

5. *Chronic toxicity*. Based on chronic testing with spinosad in the dog and the rat, the EPA has set a reference dose (RfD) of 0.027 mg/kg/day for spinosad. The RfD has incorporated a 100-fold safety factor to the NOELs found in the chronic dog study to account for inter- and intra-species variation. The NOELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOELs (systemic) shown in the rat chronic/carcinogenicity/neurotoxicity study were 9.5 and 12.0 mg/kg/day, respectively for male and female rats. Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18-month mouse feeding study and a 24-month rat feeding study at all dosages tested. The NOELs shown in the mouse oncogenicity study were 11.4 and 13.8 mg/kg/day, respectively for male and female mice. A maximum tolerated dose was achieved at the top dosage level tested in both of these studies based on excessive mortality. Thus, the doses tested are adequate for identifying a cancer risk. Accordingly, a cancer risk assessment is not needed.

6. *Animal metabolism*. There were no major differences in the bioavailability, routes or rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. Urine and fecal excretions were almost completed in 48-hours post-dosing. In addition, the routes and rates of excretion were not affected by repeated administration.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent material (spinosyn A and spinosyn D). Thus, there is no need to address metabolite toxicity.

8. *Neurotoxicity*. Spinosad did not cause neurotoxicity in rats in acute, subchronic, or chronic toxicity studies.

9. *Endocrine effects*. There is no evidence to suggest that spinosad has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. For purposes of assessing the potential dietary exposure from use of spinosad on stone fruit, cucurbits, corn (field, sweet, and pop), legume vegetables (succulent including soybeans), sorghum, and wheat as well as from other existing spinosad crop uses, a conservative estimate of aggregate exposure is determined by basing the theoretical maximum residue concentrations (TMRC) on the proposed tolerance levels for spinosad and assuming that 100% of these proposed new crops and other existing (registered for use) crops grown in the United States were treated with spinosad. The TMRC is obtained by multiplying the tolerance residue levels by the consumption data which estimates the amount of crops and related foodstuffs consumed by various population subgroups. The use of a tolerance level and 100% of crop treated clearly results in an overestimate of human exposure and a safety determination for the use of spinosad on crops cited in this summary that is based on a conservative exposure assessment.

2. *Drinking water*. Another potential source of dietary exposure are residues in drinking water. Based on the available environmental studies conducted with spinosad wherein it's properties show little or no mobility in soil, there is no anticipated exposure to residues of spinosad in drinking water.

In addition, there is no established maximum concentration level (MCL) for residues of spinosad in drinking water.

3. *Non-dietary exposure*. Spinosad is currently registered for use on a number of crops including cotton, fruits, and vegetables in the agriculture environment. Spinosad is also currently registered for outdoor use on turf and ornamentals at low rates of application (0.04 to 0.54 lb active ingredient (a.i.) per acre) and indoor use for drywood termite control (extremely low application rates used with no occupant exposure expected). Thus, the potential for non-dietary exposure to the general population is considered negligible.

D. Cumulative Effects

The potential for cumulative effects of spinosad and other substances that have a common mechanism of toxicity is also considered. In terms of insect control, spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is clearly novel and unique among known insecticidal compounds. Spinosad also has effects on the Gamma aminobatopic acid (GABA) receptor function that may contribute further to its insecticidal activity. Based on results found in tests with various mammalian species, spinosad appears to have a mechanism of toxicity like that of many amphiphilic cationic compounds. There is no reliable information to indicate that toxic effects produced by spinosad would be cumulative with those of any other pesticide chemical. Thus it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions and the proposed RfD described in Unit 1.B.5 of this document, the aggregate exposure to spinosad use on stone fruit, cucurbits, corn (field, sweet, and pop), legume vegetables (succulent including soybeans), sorghum, and wheat and other existing crop uses will utilize 25.4% of the RfD for the U.S. population. A more realistic estimate of dietary exposure and risk relative to a chronic toxicity endpoint is obtained if average (anticipated) residue values from field trials are used. Inserting the average residue values in place of tolerance residue levels produces a more realistic, but still conservative risk assessment. Based on average or anticipated residues in a dietary risk analysis, the use of spinosad on the list in this unit of pending crop uses and other existing crop uses will utilize 4.0% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Thus, it is clear that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on existing and pending crop uses.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database for spinosad relative to pre- and post-natal effects for children is complete. Further, for spinosad, the NOELs in the dog chronic feeding study which was used to calculate the RfD (0.027 mg/kg/day) are already lower than the NOELs from the developmental studies in rats and rabbits by a factor of more than 10-fold.

Concerning the reproduction study in rats, the pup effects shown at the highest dose tested were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.027 mg/kg/day is appropriate for assessing risk to infants and children.

In addition, the EPA has determined that the 10 x factor to account for enhanced sensitivity of infants and children is not needed because:

i. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or post-natal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and 2-generation reproduction in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity.

ii. No neurotoxic signs have been observed in any of the standard required studies conducted.

iii. The toxicology data base is complete and there are no data gaps.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on stone fruits, cucurbits, corn (field, sweet, and pop), legume vegetables (succulent including soybeans), sorghum and wheat and existing crop uses is 51.0% for children 1 to 6 years old, the most sensitive population subgroup. If average or anticipated residues are used in the dietary risk analysis, the use of spinosad on these crops will utilize 9.2% of the RfD for children 1 to 6 years old. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on the above proposed including existing crop uses.

F. International Tolerances

There are no Codex Maximum Residue Levels established for residues of spinosad on stone fruit, cucurbits, corn (field, sweet, and pop), legume vegetables (succulent including soybeans), sorghum, and wheat or any other food or feed crop. (Beth Edwards)

2. Zeneca Ag Products

PP 6F3344

EPA has previously received a pesticide petition (PP 6F3344) from Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE proposing pursuant to section 408(d) of the (FFDCA), 21 U.S.C 346a(d) to amend 40 CFR part 180 by establishing tolerances for the inert ingredient safener *N*,*N*-diallyl dichloroacetamide (dichlormid) of 0.05 ppm when applied to the raw agricultural commodities field corn grain, field corn fodder and field corn forage. Based on that petition EPA established time-limited tolerances on March 18, 1994, contingent upon submission of data from two chronic feeding/oncogenicity studies. The registrant provided those data on March 27, 1998, and is herein proposing that EPA extend that petition and remove the time-limitations previously imposed. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA;

however EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of dichlormid in corn plants is understood for the purposes of the proposed tolerances. The metabolism of dichlormid in corn is extensive and rapid. The principle route involves the displacement of the chlorine atoms, probably through glutathione mediated reductive dechlorination, followed by oxidation to *N,N*-diallyl glycolamide. The glycolamide is subsequently further oxidized to form the oxamic acid or conjugated with natural sugars. The presence of $^{14}CO_2$ evolved from the plants following treatment of the soil demonstrates the catabolism of the ^{14}C atom and its probable inclusion in natural biosynthetic pathways. EPA has previously determined that dichlormid is the residue of concern for tolerance setting purposes.

2. *Analytical methods*. An enforcement method is available and involves extraction, filtration, and concentration, followed by analysis by Gas Liquid Chromatography (GLC) with a selective thermionic detector. The method has been validated by the EPA at the Beltsville laboratory and included in the Pesticide Analytical Manual, Vol. II (PAM II). The validated limit of quantitation of the method allows monitoring of field corn and processed fractions at the proposed tolerances for dichloromid of 0.05 ppm.

3. *Magnitude of the residues*. Many crop residue field trials have been conducted on field corn covering the major growing areas in the United States with dichlormid applied pre emergence at application rates up to 1.0 lb a.i. per acre. In all trials dichloromid residues in grain and processed fractions were all < 0.05 ppm. In a separate trial corn was treated with two applications of dichlormid (one pre emergence and one post emergence) at a rate of 0.83 lb a.i. per acre (to simulate an exaggerated rate of 1.66 lb a.i. per acre). Samples of grain from this trial were processed under conditions which simulated commercial practice. Dichlormid residues in grain and processed fractions were all < 0.05 ppm. Dichlormid has been shown to be stable in field corn crop fractions for a minimum of 3 years when stored at -18 °C. No transfer of residues to animals through the diet is expected.

B. Toxicological Profile

1. *Acute toxicity*. Dichlormid has low acute toxicity, available data include: two rat acute oral studies with LD_{50}'s of 2,080 mg/kg for males/2,030 for females and 2,816 mg/kg for males and 2,146 mg/kg for females, respectively; a rat acute dermal study with an LD_{50} of > 2,040 mg/kg and a rabbit acute dermal study with an LD_{50} of > 5,000 mg/kg; two rat inhalation studies with LC_{50}'s of > 5.5 mg/l and > 5.6 mg/l, respectively; two primary eye irritation studies in the rabbit showing no irritation and slight irritation, respectively; two primary dermal irritation studies in the rabbit showing mild to moderate skin irritation, and a skin sensitization study which showed that dichlormid was a mild skin sensitizer in the guinea pig.

2. *Genotoxicity*. Dichlormid was not mutagenic in a range of *in vitro* assays including the Salmonella/microsome (Ames) assay, the human lymphocyte cytogenetic assay (both assays with and without metabolic activation) and an unscheduled DNA synthesis (DNA repair) assay in hepatocytes. In the L5178Y mouse lymphoma assay small increases in mutant frequency were observed only at cytotoxic concentrations and were not considered to be significant. *In vivo*, dichlormid was negative in the mouse micronucleus test and in the rat unscheduled DNA synthesis assay, when tested at the maximum tolerated dose.

3. *Developmental toxicity*. i. In an initial rat developmental effects study, previously submitted and accepted by EPA, female albino rats were dosed at 0, 10, and 40 mg/kg dichlormid in the diet from days 6 through 15 of gestation and a NOEL of 40 mg/kg/day for both maternal toxicity and developmental toxicity was determined.

ii. In a second study, rats were dosed orally by gavage with 0, 10, 40, or 160 mg/kg/day. The NOEL for maternal toxicity was 10 mg/kg/day based on a reduction in bodyweight gain and food consumption at 40 and 160 mg/kg/day. The developmental NOEL was determined to be 40 mg/kg/day based on marginal foetotoxic effects, including extra 14th ribs probably due to maternal stress, slight sternebra misalignment and some centra unossification, at 160 mg/kg/day.

iii. In an additional developmental effects study, rabbits were dosed orally by gavage with 0, 5, 30, or 180 mg/kg/day. The lowest-observed-effect level (LOEL) for both maternal and foetotoxicity was 180 mg/kg/day, characterized by reduced body weight gain and food consumption and a small increase in post-implantation loss, partial ossification and misshapen/fused sternebrae. The NOEL for both maternal and developmental toxicity was 30 mg/kg/day.

4. *Subchronic toxicity*. i. In an initial 90 day subchronic oral feeding study in the rat, previously submitted and accepted by EPA, animals were dosed at 0, 10, 40, and 160 mg/kg/day in the diet and a NOEL of 10 mg/kg/day was established.

ii. In a second study, groups of 12 male and 12 female Wistar-derived alpk: APfSD rats were fed diets containing 0, 20, 200, or 2,000 ppm dichlormid for 90 days. Significant reductions in body/weight gain and food consumption were seen in male and female rats receiving 2,000 ppm dichlormid and to a lesser degree in females at 200 ppm. The liver was identified as the principal target organ (enlargement, increased (APDM) activity in females, centrilobular hypertrophy, increased bile duct pigmentation) in the 2,000 ppm group. The NOEL was 20 ppm (equivalent to approximately 1 mg/kg/day (see discussion under Chronic toxicity in Unit 2.B.5. of this document) and the LOEL was 200 ppm, based on reduced body/weight gain and food consumption and a marginal increase in APDM activity in females and liver enlargment in males.

iii. In 90–day dog feeding study, previously submitted and accepted by EPA, animals were dosed (4 dogs/sex/dose) at 0, 1, 5, 25, and 50 mg/kg/day. The NOEL was 5 mg/kg/day and the LOEL 25 mg/kg/day based on reduced bodyweight gain, degenerative changes in voluntary muscle and increased liver weight with an associated increase in plasma alkaline phosphatase activity.

iv. In a 14-week rat inhalation study, groups of 18 Sprague-Dawley CD rats were subjected to a whole body exposure of 0, 2.0, 19.9, or 192.5 mg/m^3 for 6 hours per day, 5 days per week. The NOEL was 2.0 mg/m^3 based on histopathologic tissue alterations to the nasal olfactory epithelium at 19.9 and 192.5 mg/m^3, suggesting that dichlormid was a mild irritant to the nasal cavity. An increase in relative liver, kidney, and lung weights, that was not supported by gross or histopathological observations, was considered due to a combination of stress and inappetance at 19.9 and 192.5 mg/m^3.

5. *Chronic toxicity*. Rats (64/sex/group) were fed diets containing 0, 20, 100, or 500 ppm dichlormid (0, 1.3, 6.5, 32.5 mg/kg/day for males and 0, 1.5, 7.5, 37.5 mg/kg/day for females) for up to 2 years. At 500 ppm in both males and females there were treatment-related effects on growth and food consumption, minor reductions in

plasma triglycerides and in males, increased liver weights, accompanied by hepatocyte vaculolation and pigmentation effects. In females there was a slight overall increase in malignant tumors, primarily uterine adenocarcinomas, at 500 ppm but this specific increase was within the spontaneous incidence observed within historical control values. It was concluded that there was no evidence of oncogenicity associated with dichlormid treatment. The NOEL for chronic toxicity was 100 ppm (6.5 and 7.5 mg/kg/day for males and females respectively). In an 18-month oncogenicity study, mice (55/sex/group) were fed dichlormid at doses of 0, 10, 50, or 500 ppm (0, 1.4, 7.0, 70 mg/kg for males and 0, 1.84, 9.2, 92 mg/kg for females). At 500 ppm there was a slight increase in mortality for females from week 64 onwards and bodyweights and food utilization were reduced in males, and to a lesser extent in females. Also mice fed 500 ppm dichlormid showed non-neoplastic changes which were minor and consisted of changes in severity or incidence of common spontaneous findings. Based on these effects, the chronic NOEL was 50 ppm (7.0 and 9.2 mg/kg/day for males and females respectively). There was a marginal increase in Harderian gland adenomas in males at 500 ppm but this was considered to reflect the variable spontaneous tumor rate seen in this strain and sex of mouse. It was concluded there was no evidence of oncogenicity associated with dichormid treatment.

Based on available chronic toxicity data, Zeneca believes the RfD for dichlormid is 0.07 mg/kg/day. This RfD is based on the 2-year feeding study in rats with an NOEL of 7 mg/kg/day. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. The 2 year rat study is consistent with, but supersedes, the 90 day rat study. The 2 year rat NOEL of 7 mg/kg/day lies between 1.7 and 17 mg/kg/day derived from the NOEL and LOEL figures of 20 and 200 ppm respectively for the most recent 90 day rat study. Thus the overall NOEL in the rat for both chronic and subchronic exposure should be regarded as 7 mg/kg/day. Based on the proposed Guidelines for Carcinogenic Risk Assessment (April 23, 1996) Zeneca believes that dichlormid is not likely to be a human carcinogen, and a margin of exposure (MOE) approach should be used for human risk assessment.

6. *Animal metabolism*. In the rat dichlormid is readily absorbed and fairly rapidly excreted with extensive metabolism; the major route results in the formation of *N,N*-diallylglycolamide and its glucuronide conjugate. The glycolamide is subsequently oxidized to the *N,N*-diallyloxamic acid. An alternative pathway involves cleavage of dichlormid to form dichloroacetic acid, which was also a significant urinary metabolite. The further biotransformation of this metabolite and of *N,N*-diallyloxamic acid would lead to the observed evolution of carbon dioxide.

7. *Metabolite toxicity*. No unique plant or soil metabolites have been identified that warrant a separate toxicological assessment.

8. *Endocrine disruption*. No specific tests have been conducted with dichlormid to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there is no overall trend in the toxicology database that indicates that dichlormid would have endocrine disrupting activity.

C. Aggregate Exposure

1. *Food*. To assess the potential dietary exposure using the proposed tolerances of 0.05 ppm, Zeneca has estimated the aggregate exposure based on the theoretical maximum residue contribution (TMRC). This is a highly conservative over-estimation of human exposure, based on tolerance level residues (0.05 ppm) and 100% crop treated. The analysis was determined using the DEEM software and the USDA CSF II 94–95 data.

2. *Drinking water*. Dichlormid is very rapidly degraded in soil (laboratory measured aerobic half life of 8 days), and applied at a maximum rate of 1.0 lb/acre, so despite only exhibiting moderate adsorption to soil, (Koc 36–49), the leaching potential for dichlormid to reach ground water is expected to be low. The impact of the interactive processes of adsorption and degradation on leaching have been assessed using EPA mathematical models of pesticide movement in soil.

Drinking water estimate concentrations (DWEC) were calculated using (SCI-GROW) and (GENEEC). These predict a ground water concentration of 0.02 ppb, and surface water concentrations of 49.71 ppb for an instaneous peak and 49.27 for a 56 day average. Drinking water levels of concern (DWLOC) were calculated for both chronic and acute exposure according to the EPA (SOP). All the values are less than the DWEC. As EPA believes there is negligible risk at values less than 100% of the DWEC, Zeneca does not expect exposure to dichlormid residues in drinking water to be a concern.

3. *Non-dietary exposures*. As dichlormid is used only on agricultural crops and is not used in or around the home, exposure to the general population is unlikely.

D. Cumulative Effects

Zeneca has considered the potential for cumulative effects of dichlormid and other substances that have a common mechanism of toxicity. Zeneca does not have any reliable information to suggest that dichlormid has any toxic effects that arise from toxic mechanisms, that are common to other substances. Therefore, a consideration of common mechanism and cumulative effects with other substances is not appropriate for dichlormid and Zeneca is considering only the potential risks of dichlormid in this exposure assessment.

E. Safety Determination

1. *U.S. population*—i. *Chronic risk*. Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data base for dichlormid, Zeneca has calculated the aggregate exposure will be 0.1% (0.00006 mg/kg/day) of the RfD (0.07 mg/kg/day) for the U.S population. The most highly exposed subgroup is non-nursing infants a TMRC of 0.000149 mg/kg/day or 0.27% of the RfD. As EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health, Zeneca concludes that there is a reasonable certainty that no harm will result from aggregate exposure to dichlormid residues.

ii. *Acute risk*. The acute toxicity of dichlormid is low, and there are no concerns for acute-dietary, occupational or non-occupational exposures to dichlormid.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of dichlormid, data from developmental toxicity studies in the rat and rabbit have been considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. There was no evidence to suggest that dichlormid was a developmental toxicant in either the rat or rabbit. It was also observed that there was no risk below maternally toxic doses as the NOEL for developmental effects in the rat was 40 mg/kg/day as opposed to the maternal NOEL of 10

mg/kg/day and, in the rabbit study, the NOEL for both maternal and developmental effects was 30 mg/kg/day. For both these reasons, and the fact that the RfD is based on the chronic rat study which has a NOEL considerably lower than the developmental NOELs, Zeneca believes that an additional uncertainty factor is not warranted for the safety of infants and children. Reliable data supports the use of a 100-fold uncertainty factor (MOE) to account for inter-species extrapolation and intra-species variability which will be appropriate to protect infants and children. Using the same conservative exposure assumptions used for the determination in the general population, Zeneca has concluded that the percentage of RfD that will be utilized by aggregate exposure to dichlormid is 0.2% for non-nursing infants (the group at highest risk). Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Zeneca concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to dichlormid residues.

F. International Tolerances

A Maximum Residue Level has not been established for dichlormid by the Codex Alimentarius Commission. (Treva Alston)

[FR Doc. 98–24840 Filed 9–15–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PB–402404–OK; FRL–6027–3]

Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; State of Oklahoma's Authorization Application

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice; request for comments and opportunity for a public hearing.

SUMMARY: On August 10, 1998, the State of Oklahoma submitted an application for EPA approval to administer and enforce training and certification requirements, training program accreditation requirements, and work practice standards for lead-based paint activities in target housing and child-occupied facilities under section 402 of the Toxic Substances Control Act (TSCA). This notice announces the receipt of Oklahoma's application, and provides a 45–day public comment period and an opportunity to request a public hearing on the application. Oklahoma has provided a certification that this program meets the requirements for approval of a State program under section 404 of TSCA. Therefore, pursuant to section 404, the program is deemed authorized as of the date of submission. If EPA finds that the program does not meet the requirements for approval of a State program, EPA will disapprove the program, at which time a notice will be issued in the **Federal Register** and the Federal program will be established.

DATES: The State program became effective August 10, 1998. Submit comments on the authorization application on or before November 2, 1998. Public hearing requests must be submitted on or before September 30, 1998.

If a public hearing is requested and granted, the hearing will be held on October 7, 1998, at 1 p.m., at the Oklahoma Department of Environmental Quality, 707 North Robinson, Multi-Purpose Room, 1st Floor, Oklahoma City, Oklahoma. If a public hearing is not requested, this meeting time and place will be canceled. Therefore, individuals are advised to verify the status of the public hearing by contacting the Regional Lead Coordinator at the telephone number or address provided in the ''FOR FURTHER INFORMATION CONTACT'' unit of this notice after September 30, 1998 and before the October 7, 1998, scheduled public hearing date.

ADDRESSES: Submit all written comments and/or requests for a public hearing identified by docket control number ''PB–402404–OK'' (in duplicate) to: Environmental Protection Agency, Region 6, 6PD-T, 1445 Ross Avenue., Suite 1200, Dallas, TX 75202-2733.

Comments, data, and requests for public hearing may also be submitted electronically to robinson.jeffrey@epamail.epa.gov. Follow the instructions under Unit IV. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: Jeffrey Robinson, Regional Lead Coordinator, 1445 Ross Avenue, Suite 1200, 6PD-T, Dallas, TX 75202-2733. telephone: 214–665–7577; e-mail address: robinson.jeffrey@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On October 28, 1992, the Housing and Community Development Act of 1992, Pub. L. 102-550, became law. Title X of that statute was the Residential Lead-Based Paint Hazard Reduction Act of 1992. That Act amended TSCA (15 U.S.C. 2601 *et seq.*) by adding Title IV (15 U.S.C. 2681-92), entitled Lead Exposure Reduction.

Section 402 of TSCA (15 U.S.C. 2682) authorizes EPA to promulgate final regulations governing lead-based paint activities. Lead-based paint activities is defined in Section 402(b) of TSCA and authorizes EPA to regulate lead-based paint activities in target housing, public buildings built prior to 1978, commercial buildings, bridges and other structures or superstructures. Those regulations are to ensure that individuals engaged in such activities are properly trained, that training programs are accredited, and that individuals engaged in these activities are certified and follow documented work practice standards. Under section 404 of TSCA, a State may seek authorization from EPA to administer and enforce its own lead-based paint activities program.

On August 29, 1996 (61 FR 45777) (FRL–5389–9), EPA promulgated final TSCA section 402/404 regulations governing lead-based paint activities in target housing and child-occupied facilities (a subset of public buildings). Those regulations are codified at 40 CFR part 745, and allow both States and Indian Tribes to apply for program authorization. On August 31, 1998, EPA will institute the Federal program in States or Indian Country without an authorized program, as provided by section 404(h) of TSCA.

States and Indian Tribes that choose to apply for program authorization must submit a complete application to the appropriate Regional EPA office for review. Those applications will be reviewed by EPA within 180 days of receipt of the complete application. To receive EPA approval, a State or Indian Tribe must demonstrate that its program is at least as protective of human health and the environment as the Federal program, and provides adequate enforcement (section 404(b) of TSCA, 15 U.S.C. 2684(b)). EPA's regulations (40 CFR part 745, subpart Q) provide the detailed requirements a State or Tribal program must meet in order to obtain EPA approval.

A State may choose to certify that its lead-based paint activities program meets the requirements for EPA approval by submitting a letter signed by the Governor or Attorney General stating that the program meets the requirements of section 404(b) of TSCA. Upon submission of such certification letter, the program is deemed authorized until such time as EPA disapproves the program application or withdraws the authorization.

Section 404(b) of TSCA provides that EPA may approve a program application only after providing notice and an opportunity for a public hearing on the application. Therefore, by this notice EPA is soliciting public comment on whether Oklahoma's application meets the requirements for EPA approval. This notice also provides an opportunity to request a public hearing on the application. Oklahoma has provided a self-certification letter from the Governor that its program meets the requirements for approval of a State program under section 404 of TSCA. Therefore, pursuant to section 404, the program is deemed authorized as of the date of submission. If EPA finds that the program does not meet the requirements for approval of a State program, EPA will disapprove the program, at which time a notice will be issued in the **Federal Register** and the Federal program will be established in Oklahoma.

II. State Program Description Summary

The lead-based paint program is administered by the Air Quality Division (AQD) within the Department of Environmental Quality (DEQ). The program is staffed by the Special Air Projects Unit. The lead-based paint program duties include enforcement, compliance assistance, inspections, certification, accreditation, and public education.

The Oklahoma Lead-Based Paint Management Rules (Rules) incorporate by reference the Federal accreditation requirements in 40 CFR 745.225, except those paragraphs that address application dates, accreditation deadlines, accredited training courses, programs that offer only refresher training courses, renewal timelines, and renewal deadlines. In addition to providing the various dates, timelines, and deadlines not incorporated by reference from the Federal rule, the Rules limit accreditation to educational institutions and government agencies that offer ongoing and continuous lead-based paint training programs. In addition to the incorporations by reference, Oklahoma rules provide for provisional accreditation. A stakeholder task force strongly recommended an on-site evaluation of the training program prior to issuing final accreditation in order to ensure that the training organization operates according to the information given in the accreditation application. Provisional accreditation allows the training facility to provide training under the conditions outlined in Oklahoma Administrative Code (OAC) 252:11 9-5. The DEQ further ensures quality training by requiring an on-site evaluation before final accreditation is issued.

Refresher courses can be accredited only if the training program has received accreditation for the initial discipline-specific training course. Programs that have been accredited by another State or agency must apply for and receive accreditation from DEQ before conducting or advertising a training course in Oklahoma. An accredited training program must notify the DEQ of course offerings, significant changes in the program, course cancellations and personnel changes. Annual review is required and is based on documented implementation of compliance updates as well as satisfactory course and instructor evaluations.

The Rules also incorporate by reference the Federal certification requirements in 40 CFR 745.226, except for those paragraphs that address application dates, enforcement dates, interim certification, certification based on prior training, re-certification, and certification of firms. Certification is required for all individuals and firms who perform lead-based paint activities or services in target housing and child-occupied facilities pursuant to OAC 252:110-5-1(3), 110-7, and 110-11. In addition, to providing the various dates not incorporated by reference, the Rules require that applicants receive training from a DEQ-accredited lead-based paint training program and that the certifications be renewed annually. The appropriate certification exam must be taken every 3 years. Applicants who completed the required training prior to the availability of a DEQ-accredited course must take a DEQ-accredited refresher course and pass the appropriate certification exam. Persons holding a valid certification issued by another State or Agency must apply for certification, but may request a waiver of initial training requirements. However, a DEQ-accredited refresher course must be taken. Firms that perform lead-based paint services must be certified by the DEQ and must employ properly certified employees.

The Federal work practice standards at 40 CFR 745.227 have been incorporated by reference, with the exception of the performance dates. The Rules prohibit the clearance testing of a project by any person who has an economic relationship with the abatement project contractor. The DEQ must be notified in advance of the start of an abatement project, and quarterly reports of lead-based paint activities or service performed by certified persons must be submitted to DEQ. Only laboratories accredited by the National Lead Laboratory Accreditation Program (NLLAP) recognized by EPA may conduct required analyses, but X-ray fluorescence may be used for on-site lead detection.

Oklahoma has submitted information in the application addressing the required program elements for State lead-based paint activities programs pursuant to 40 CFR 745.325. In addition, Oklahoma has submitted information detailing their lead-based paint compliance and enforcement programs as required by 40 CFR 745.327. At this time, Oklahoma is not seeking authorization of a pre-renovation notification program pursuant to 40 CFR 745.326.

III. Federal Overfiling

TSCA section 404(b) makes it unlawful for any person to violate, or fail or refuse to comply with, any requirement of an approved State or Tribal program. Therefore, EPA reserves the right to exercise its enforcement authority under TSCA against a violation of, or a failure or refusal to comply with, any requirement of an authorized State or Tribal program.

IV. Public Record and Electronic Submissions

The official record for this action, as well as the public version, has been established under docket control number ''PB–402404–OK.'' Copies of this notice, the State of Oklahoma's authorization application, and all comments received on the application are available for inspection in the Region 6 office, from 7:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket is located at the EPA Region 6 Library, Environmental Protection Agency, 1445 Ross Ave., Suite 1200, Dallas, TX.

Commenters are encouraged to structure their comments so as not to contain information for which Confidential Business Information (CBI) claims would be made. However, any information claimed as CBI must be marked ''confidential,'' ''CBI,'' or with some other appropriate designation, and a commenter submitting such information must also prepare a nonconfidential version (in duplicate) that can be placed in the public record. Any information so marked will be handled in accordance with the procedures contained in 40 CFR part 2. Comments and information not claimed as CBI at the time of submission will be placed in the public record.

Electronic comments can be sent directly to EPA at: robinson.jeffrey@epamail.epa.gov. Electronic comments must be submitted

as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number ''PB–402404–OK.'' Electronic comments on this document may be filed online at many Federal Depository Libraries. Information claimed as CBI should not be submitted electronically.

V. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

EPA's actions on State or Tribal lead-based paint activities program applications are informal adjudications, not rules. Therefore, the requirements of the Regulatory Flexibility Act (RFA, 5 U.S.C. 601 *et seq.*), the Congressional Review Act (5 U.S.C. 801 *et seq.*), Executive Order 12866 (''Regulatory Planning and Review,'' 58 FR 51735, October 4, 1993), and Executive Order 13045 (''Protection of Children from Environmental Health Risks and Safety Risks,'' 62 FR 1985, April 23, 1997), do not apply to this action. This action does not contain any Federal mandates, and therefore is not subject to the requirements of the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538). In addition, this action does not contain any information collection requirements and therefore does not require review or approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

B. Executive Order 12875

Under Executive Order 12875, entitled ''Enhancing Intergovernmental Partnerships'' (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or Tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local, and Tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's action does not create an unfunded Federal mandate on State, local, or Tribal governments. This action does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this action.

C. Executive Order 13084

Under Executive Order 13084, entitled ''Consultation and Coordination with Indian Tribal Governments'' (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's action does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this action.

Authority: 15 U.S.C. 2682, 2684.

List of Subjects

Environmental protection, Hazardous substances, Lead, Reporting and recordkeeping requirements.

Dated: September 3, 1998.

Robert E. Hannesschlager,

Acting Division Director, Multimedia Planning and Permitting, Region VI.

[FR Doc. 98–24841 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Submitted to OMB for Review and Approval

September 10, 1998.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated information techniques or other forms of information technology.

DATES: Written comments should be submitted on or before October 16, 1998. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications, Room 234, 1919 M St., NW, Washington, DC 20554 or via internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at 202–418–0217 or via internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–0654.

Title: Application for a Multipoint Distribution Service Authorization.

Form Number: FCC 304.

Type of Review: Revision of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents: 500.

Estimated Time Per Response: 1 hour.

Frequency of Response: On occasion reporting requirements; Third party disclosure.

Total Annual Burden: 500 hours.

Cost to Respondents: $1,495,000.

Needs and Uses: FCC Form 304 will be used by existing MDS operators to modify their stations or to add a signal booster station. It will also be used by some winning bidders in the competitive bidding process to propose facilities to provide wireless cable service over any usable MDS channels within their Basic Trading Area (BTA). The Commission has revised the FCC Form 304 to further streamline the application process and to accommodate electronic filing. This collection of information also includes the burden for the technical rules involving the interference or engineering analysis and service requirements under Sections 21.902, 21.913 and 21.938. These analyses will not be submitted with the application but will be retained by the operator and must be made available to the Commission upon request. The data are used by FCC staff to ensure that the applicant is legally, technically and otherwise qualified to become a Commission licensee. MDS/ITFS applicants/licensees will need this information to perform the necessary analyses of the potential for harmful interference to their facility.

OMB Approval Number: 3060–0664.

Title: Certification of Completion of Construction for a Multipoint Distribution Service Station.

Form Number: FCC 304–A.

Type of Review: Revision of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents: 300.

Estimated Time Per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirements.

Total Annual Burden: 150 hours.

Cost to Respondents: $0.

Needs and Uses: FCC Form 304–A will be used to certify that the facilities as authorized in FCC Form 304 have been completed and that the station is now operational, ready to provide service to the public. The Commission has revised FCC Form 304 to further streamline the application process and to accommodate electronic filing. Each licensee will specify as a condition that upon completion of construction, the licensee must file with the Commission an FCC Form 304–A, certifying that the facilities as authorized has been completed and that the station is now operational and ready to provide service to the public. The conditional license shall be automatically forfeited upon the expiration of the construction period specified in the license unless within five days after that date an FCC Form 304–A has been filed with the Commission.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98–24807 Filed 9–15–98; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0043]

Submission for OMB Review; Comment Request Entitled Appraisal, Fair Annual Rental for Parking Spaces

AGENCY: Public Buildings Service, GSA.

ACTION: Notice of request for an extension to an existing OMB clearance (3090–0043).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Office of Acquisition Policy has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Appraisal, Fair Annual Rental for Parking Spaces. The information collection was previously published in the **Federal Register** on July 9, 1998 at 63 FR 37117, allowing for a 60-day public comment period. No comments were received.

DATES: Comment Due Date: October 16, 1998.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: Edward Springer, GSA Desk Officer, Room 3235, NEOB, Washington, DC 20503, and also may be submitted to Marjorie Ashby, General Services Administration, (MVP), 1800 F Street NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: William C. Wyrick, Public Buildings Service (202) 501–4407.

SUPPLEMENTARY INFORMATION:

A. Purpose

The GSA is requesting the Office of Management and Budget (OMB) to review and approve information collection, 3090–0043, concerning Appraisal, Fair Annual Rental for Parking Spaces. This form is needed by contract and staff appraisers to estimate the assessed parking rates for agencies occupying space in Federal and private buildings.

B. Annual Reporting Burden

Respondents: 260; annual responses: 1300; average hours per response: 1.6; burden hours: 2200.

Copy of Proposal

A copy of this proposal may be obtained from the GSA Acquisition Policy Division (MVP), Room 4011, GSA Building, 1800 F Street NW., Washington, DC 20405, or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: September 10, 1998.

Ida M. Ustad,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 98–24806 Filed 9–15–98; 8:45 am]

BILLING CODE 6820–61–M

GENERAL SERVICES ADMINISTRATION

President's Commission on the Celebration of Women in American History

AGENCY: General Services Administration.

ACTION: Meeting Notice.

SUMMARY: Notice is hereby given that the President's Commission on the Celebration of Women in American History will hold an open meeting from 9:00 a.m. to 4:00 p.m. on Friday, September 25, 1998 at the Albuquerque Museum Auditorium, 200 Mountain Road, NW., Albuquerque, NM 87104.

PURPOSE: The meeting is called to update members on committee operations and activities.

FOR FURTHER INFORMATION CONTACT:

Martha Davis (202) 501–0705, Assistant to the Associate Administrator for Communications, General Services Administration.

Under 41 CFR 101–6.1015(b)(2) less than 15 days notice of the meeting is provided due to delays in organizing schedules.

Dated: September 10, 1998.

Beth Newburger,

Associate Administrator for Communications.

[FR Doc. 98–24805 Filed 9–15–98; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of a Cooperative Agreement With the Summit Health Institute for Research and Education, Inc.

The Office of Minority Health (OMH), Office of Public Health and Science, announces that it will enter into an umbrella cooperative agreement with the Summit Health Institute for Research and Education, Inc. (SHIRE). This cooperative agreement is an umbrella cooperative agreement and will establish the broad programmatic framework in which specific projects can be supported by various agencies during the project period.

The purpose of this cooperative agreement is to assist SHIRE to expand and enhance its technical assistance, information dissemination, networking, health services research and program evaluation activities. These activities will maximize the beneficial impact of Government policies and programs with respect to African Americans, particularly health care consumers. It is anticipated that future activities will focus on programs and policies aimed at improving the overall health status of African Americans in order to eliminate the health gaps that exist between African Americans and other racial/ethnic groups. OMH will provide consultation, including administrative and technical assistance as needed, for the execution and evaluation of all aspects of this cooperative agreement. OMH will also participate and/or collaborate with the awardee in any workshops or symposia to exchange current information, opinions and research findings during this agreement.

Authorizing Legislation

The cooperative agreement is authorized under Section 1707(d)(1) of the Public Health Service Act.

Background

Assistance will be provided only to Summit Health Institute for Research and Evaluation, Inc. (SHIRE). No other applications are solicited. OMH believes SHIRE is uniquely qualified to accomplish the objectives of this cooperative agreement because it:

1. Serves as the principal resource and technical advisor to the National Black Caucus of Elected Officials and the National Association of Black County Officials with respect to managed care, particularly Medicaid managed care;

2. Works closely with community based organizations to increase the knowledge and participation of African Americans concerning Medicaid and managed care;

3. Currently is working with community-based organizations to implement the Children's Health Insurance Program;

4. Has a high level of experience in organizing health consumers, providers, community-based organizations and faith institutions to ensure that African American beneficiaries participate more fully in Federal/state-funded health-related programs;

5. Provides technical assistance to state-wide associations regarding implementation of state and Federal programs (e.g., Medicaid 1115 Waivers);

6. Collaborates with non-governmental organizations in the development of tracking technology designed to prevent fraud and abuse, as well as systems to follow patients from one medical facility to another and from one payment status to another;

7. Prepares the annual publication of resource documents for African American groups, organizations and individuals involved in health-related issues. SHIRE has conducted and compiled results of research on current Federal and state programs and policy issues; the role and functions of key Federal agencies; available information on African American health care providers and consumers; quality, cost, utilization and insurance data; national and state trends; community-based initiatives and available resources; and recent mortality and morbidity statistics.

This cooperative agreement will be awarded for a 12-month budget period within a project period of 5 years. Depending upon the types of projects and availability of funds, it is anticipated that this cooperative agreement will receive approximately $50,000 to $100,000. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Where to Obtain Additional Information

If you are interested in obtaining additional information regarding this project, contact Ms. Georgia Buggs, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, Maryland 20852 or telephone (301) 443–5084.

Dated: September 4, 1998.

Tuei Doong,

Deputy Director, Office of Minority Health.

[FR Doc. 98–24755 Filed 9–15–98; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made a final finding of scientific misconduct in the following case:

George A.S. Park, M.S., Wadsworth Center, New York State Department of Health: Based on Mr. Park's own admission, information obtained by the Office of Research Integrity (ORI) during its oversight review, and a report prepared by the Wadsworth Center, New York State Department of Health, dated October 23, 1997, and accepted by the University at Albany, State University of New York, the awardee institution, ORI found that Mr. Park, former research technician, Wadsworth Center, New York State Department of Health, engaged in scientific misconduct in research supported by a grant from the National Institute of Environmental Sciences (NIEHS), National Institutes of Health (NIH). ORI acknowledges Mr. Park's cooperation with the Wadsworth Center.

Specifically, Mr. Park falsified high pressure liquid chromatography data. The data were collected over an eight-month period in connection with a project to demonstrate the estrogen-like neurochemical and reproductive effects of the major metabolite of 3,4,3',4'-Tetrachlorobiphenyl. The falsified data were presented at the Dioxin '97 conference in Indianapolis, Indiana, in August 1997 and published with the conference proceedings in Organohalogen Compounds 34:125–128 (1997). The conference organizer was notified of the falsifications in the presented data and published abstract.

Mr. Park has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the three (3) year period beginning August 31, 1998:

(1) To exclude himself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That any institution that submits an application for PHS support for a research project on which his participation is proposed or which uses him in any capacity on PHS supported research, or that submits a report of

PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Mr. Park's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 98–24794 Filed 9–15–98; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO–98–28]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

1. Diabetes Today National Training Center. A contract to refine, present, and evaluate a diabetes training course—New—The National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation, proposes to conduct a training center. Diabetes is a complex chronic disease. The successful management of this disease requires a comprehensive support system that includes proper medical treatment, behavior and lifestyle changes that maintain recommended blood glucose levels, blood pressure, weight and physical activity, and community awareness and programs that facilitate the adoption of these behaviors.

The National Centers for Disease Control and Prevention, Division of Diabetes Translation has developed and presented a training course for health professionals and community leaders to provide training and follow-up in implementing community activities to control diabetes. The course, Diabetes Today, is a structured curriculum that incorporates principles of community organization, community health education and adult learning in a training program for health professionals. This contract will provide, revise, and evaluate Diabetes Today in the continental United States, Puerto Rico and the Virgin Islands. Focus groups will be conducted to evaluate the effectiveness of the training course and to determine needs in communities. Most of those in the focus groups will be participants in the training courses. The data will not be available from any other source. There is no cost to respondents.

Respondents	No. of respondents	No. of responses/respondent	Average burden response (in hrs.)	Total burden (in hrs.)
Bilingual public health workers	*10	1	1	10
Participants in Diabetes Today trainings	*20	1	1	20
Total				30

*Estimates. Contractor will develop instruments and arrange focus groups.

2. Diabetes Today, Regional Training Center, A contract to adapt a diabetes training program to the needs of Hawaii and the Pacific Basin—New—The National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation, proposes to conduct a training center. Diabetes is a complex chronic disease. The successful management of this disease requires a comprehensive support system that includes proper medical treatment, behavior and lifestyle changes to maintain recommended blood glucose levels, blood pressure, weight and physical activity, and community awareness and programs that facilitate the adoption of these behaviors.

The National Centers for Disease Control and Prevention, Division of Diabetes Translation, has developed and presented a training course for health professionals and community leaders to provide training and follow-up in implementing community activities to control diabetes. Most of this activity has taken place in the Continental United States. A contract has been offered to adapt this material to the cultures of Hawaii and the Pacific Basin. Focus groups will be conducted to determine needs in diabetes education and to adapt the course to the needs of individual Pacific cultures. Focus group data will be analyzed using accepted, content analysis methods. Evaluation will be conducted with the goal of providing culturally relevant training in community organization to reduce the burden of diabetes in the Pacific Region. The information developed is not available from other sources. There is no cost to respondents.

Respondents	No. of respondents	No. of responses/respondent	Average burden response (in hrs.)	Total burden (in hrs.)
Hawaii and Pacific Islanders with Diabetes	80 (10 focus groups of 8 persons each)*	1	1	80
Total	.....	.....	.....	80

*These are estimates. Instruments will be developed and focus groups arranged by contractor.

3. Cycle 6 of the National Survey of Family Growth (NSFG–6) (0920–0314)—Revision—The National Survey of Family Growth has been conducted periodically since 1973 by the National Center for Health Statistics, CDC. The first five cycles of the NSFG were based on interviews with women 15–44 years of age, to measure factors related to birth and pregnancy rates and maternal and infant health. In Cycle 6, both women and men will be interviewed. The interviews with males 15–49 will address (1) factors that affect entry into fatherhood and the intendedness of births; (2) factors that affect the spread of Sexually Transmitted Diseases (STDs) and HIV (Human Immunodeficiency Virus, the virus that causes AIDS); and (3) factors that affect men's ability and willingness to carry out their fatherhood roles, including the payment of child support.

In late 2000 or early 2001, the NSFG will interview a nationally representative sample of 11,800 women and 7,200 men. Black, Hispanic, and 15–24-year-old men and women will be sampled at a higher rate than others. A pretest/pilot study of 600 females and 600 males is needed to test procedures for collecting sensitive data. All participation will be completely voluntary and confidential.

NSFG data help measure the demographics, health status, and behavior of the population of reproductive age (as well as those responsible for most STDs). The NSFG data from the 1995 survey have already been published in 4 major NCHS reports and the January/February 1998 issue of the journal Family Planning Perspectives. Besides NCHS, users of NSFG data include the DHHS Office of Population Affairs, the National Institute for Child Health and Human Development, the CDC and NIH HIV/AIDS programs, and the Children's Bureau. Other users include Congress (for Sections 905 and 906 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, among others); the Healthy People 2000 and 2010 initiatives, private researchers in demography, public health, maternal and child health, and state governments. Males are being added to the survey in response to the recent report, *Nurturing Fatherhood: Improving Data and Research on Male Fertility, Family Formation, and Fatherhood*, released by the Federal Interagency Forum on Child and Family Statistics. There is no cost to respondents.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (hrs.)	Total burden (in hrs.)
.				
Pretest: screener	2000	1	0.08	167
Pretest: males	600	1	1.00	600
Pretest: females	600	1	1.33	800
Cognitive Testing	200	1	1.00	200
Survey: screener	40000	1	0.08	3,320
Survey: males	7200	1	1.00	7,200
Survey: females	11800	1	1.33	15,729
Total	.....	.....	.....	28,016

Dated: September 2, 1998.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–24835 Filed 9–15–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER).

Time and Date: 8 a.m.–5 p.m., September 24, 1998.

Place: Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC 20008, telephone 202/234–0700, FAX 202/756-5120.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary, Health and Human Services (HHS); the Assistant Secretary for Health; the Director, CDC; and the Administrator, Agency for Toxic Substances and Disease Registry, on the establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies.

Matters To Be Discussed: Agenda items include discussions of public health implications of the report from the Institute of Medicine's Committee on Thyroid Screening Related to I–131 Exposure and the National Academy of Sciences' Committee on Exposure of the American People to I–131 from the Nevada Atomic Bomb Tests, and the ACERER Subcommittee for Community Affairs recommendations.

Agenda items are subject to change as priorities dictate.

An unavoidable administrative delay prevented meeting the 15-day publication requirement.

Contact Person for More Information: Michael J. Sage, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: September 11, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–24894 Filed 9–15–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0747]

Agency Information Collection Activities: Proposed Collection; Comment Request; Customer/Partner Service Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on voluntary customer/partner service surveys to implement Executive Order 12862.

DATES: Submit written comments on the collection of information by November 16, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Customer/Partner Service Surveys

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research relating to regulated articles and to conduct educational and public information programs relating to responsibilities of the agency. Executive Order 12862, entitled ''Setting Customer Service Standards,'' directs Federal agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys will be voluntary. This request covers customer service surveys or regulated entities, such as food processors; cosmetic, drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers partner surveys of State and local governments.

FDA will use the information gathered from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will assess timeliness, appropriateness, accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA projects 14 customer/partner service surveys per year, with a sample of between 50 and 6,000 customers each. Some of these surveys will be repeats of earlier surveys, for purposes of monitoring customer/partner service and developing long-term data.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Responses	Total Hours
Mail/telephone surveys	20,000	1	.30	6,000
Total				6,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the number of customer/partner service surveys FDA has conducted since January 26, 1998.

Dated: September 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24753 Filed 9–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0748]

Agency Emergency Processing Request Under OMB Review; Attitudinal and Behavorial Efffects of Direct-To-Consumer Advertising of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). This notice solicits comments on a survey of the public to examine the impact of direct-to-consumer (DTC) advertising.

DATES: Submit written comments on the collection of information by September 28, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13 by September 28, 1998, because this information is essential to the agency's mission. The agency cannot reasonably comply with the provisions of the PRA because the use of normal clearance procedures would prevent this collection of information from being carried out in a timely manner. FDA needs information about consumers' reactions to and behaviors that stem from DTC prescription drug advertising in order to develop policy on appropriate requirements for disclosure of risk and efficacy information about the drugs. In August 1997, when the agency issued its draft guidance on consumer-directed broadcast advertisements, FDA announced its intention to evaluate the effects of the guidance and of DTC promotion in general within 2 years of finalizing the guidance. FDA is currently in the process of finalizing this guidance. In addition, the amount of prescription drug DTC advertising is growing so quickly that rapid assessment of the public is required in order to assess public response before such advertising increases further. The information to be collected on consumer exposure and response to prescription drug DTC advertising is needed: (1) As a baseline measurement against which the effects of the final guidance will be evaluated and (2) as a timely and immediate assessment of consumers' initial response to the already high and rapidly increasing level of prescription drug DTC advertising.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Attitudinal and Behavioral Effects of Direct-To-Consumer (DTC) Advertising of Prescription Drugs

Under the Food, Drug, and Cosmetic Act (the act), FDA has responsibility to ensure that the labeling and advertising of prescription drugs is truthful and not misleading. Section 502(n) of the act (21 U.S.C. 352(n)) prohibits the advertising of prescription drugs that is false or misleading or that fails to provide a ''brief summary'' of products' risks. Although advertising of prescription drugs was once restricted to health professionals, consumers increasingly have become a primary target audience, and DTC advertising has dramatically increased in the past few years. However, DTC advertising raises many questions and issues. While bringing new information to consumers, it also may confuse consumers, and no rigorous research has been done about the effects of DTC on health professional-patient relationships, compliance, or the health-care system, despite a request by FDA at a public hearing on DTC in October 1995. This data collection by FDA will serve as a baseline prior to increased advertising of prescription drugs expected in the near future.

A national randomized telephone survey will be conducted with 1,000 adults 18 years of age and over who recently visited a physician. Respondents will be asked their views about any prescription drug they may have received and prescription drugs in general, and their attitudes and behavior in relation to DTC advertising, including any visits to a health professional. In a followup mail survey, respondents will be sent a questionnaire with a variety of print DTC ads. They will be asked to rate their familiarity with the advertisements. The information from this data collection is needed to help FDA make policy decisions about disclosure requirements for promoting prescription drugs DTC.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11,000 (screener)	1	11,000	.017	183.3
1,000 (survey)	1	1,000	.317	317.0
1,000 (mail followup)	1	1,000	.167	167.0
Total Burden				667.3

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24796 Filed 9–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0174]

International Conference on Harmonisation; Guidance on Statistical Principles for Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''E9 Statistical Principles for Clinical Trials.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to provide recommendations to sponsors and scientific experts regarding statistical principles and methodology which, when applied to clinical trials for marketing applications, will facilitate the general acceptance of analyses and conclusions drawn from the trials.

DATES: Effective September 16, 1998. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert O'Neill, Center for Drug Evaluation and Research (HFD–700), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3195.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are: The European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of May 9, 1997 (62 FR 25712), FDA published a draft tripartite guideline entitled ''Statistical Principles for Clinical Trials'' (E9). The notice gave interested persons an opportunity to submit comments by June 23, 1997.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on February 5, 1998.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this document has been designated a guidance, rather than a guideline.

The guidance addresses principles of statistical methodology applied to clinical trials for marketing applications. The guidance provides recommendations to sponsors for the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The document also provides guidance to scientific experts in preparing application summaries or assessing evidence of efficacy and safety, principally from late Phase II and Phase III clinical trials. Application of the principles of statistical methodology is intended to facilitate the general acceptance of analyses and conclusions drawn from clinical trials.

This guidance represents the agency's current thinking on statistical principles for clinical trials of drugs and biologics.

It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or at CBER's World Wide Web site at ''http://www.fda.gov/cber/publications.htm''.

The text of the guidance follows:

E9 Statistical Principles for Clinical Trials [1]

Note: A glossary of terms and definitions is provided as an annex to this guidance.

I. Introduction

1.1 Background and Purpose

The efficacy and safety of medicinal products should be demonstrated by clinical trials that follow the guidance in ''Good Clinical Practice: Consolidated Guideline'' (ICH E6) adopted by the ICH, May 1, 1996. The role of statistics in clinical trial design and analysis is acknowledged as essential in that ICH guideline. The proliferation of statistical research in the area of clinical trials coupled with the critical role of clinical research in the drug approval process and health care in general necessitate a succinct document on statistical issues related to clinical trials. This guidance is written primarily to attempt to harmonize the principles of statistical methodology applied to clinical trials for marketing applications submitted in Europe, Japan, and the United States.

As a starting point, this guidance utilized the CPMP (Committee for Proprietary Medicinal Products) Note for Guidance entitled ''Biostatistical Methodology in Clinical Trials in Applications for Marketing Authorizations for Medicinal Products'' (December, 1994). It was also influenced by ''Guidelines on the Statistical Analysis of Clinical Studies'' (March 1992) from the Japanese Ministry of Health and Welfare and the U.S. Food and Drug Administration document entitled ''Guideline for the Format and Content of the Clinical and Statistical Sections of a New Drug Application'' (July 1988). Some topics related to statistical principles and methodology are also embedded within other ICH guidances, particularly those listed below. The specific guidance that contains related text will be identified in various sections of this document.

E1A: The Extent of Population Exposure to Assess Clinical Safety

E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

E2B: Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

E2C: Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs

E3: Structure and Content of Clinical Study Reports

E4: Dose-Response Information to Support Drug Registration

E5: Ethnic Factors in the Acceptability of Foreign Clinical Data

E6: Good Clinical Practice: Consolidated Guideline

E7: Studies in Support of Special Populations: Geriatrics

E8: General Considerations for Clinical Trials

E10: Choice of Control Group in Clinical Trials

M1: Standardization of Medical Terminology for Regulatory Purposes

M3: Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals.

This guidance is intended to give direction to sponsors in the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The document will also assist scientific experts charged with preparing application summaries or assessing evidence of efficacy and safety, principally from clinical trials in later phases of development.

1.2 Scope and Direction

The focus of this guidance is on statistical principles. It does not address the use of specific statistical procedures or methods. Specific procedural steps to ensure that principles are implemented properly are the responsibility of the sponsor. Integration of data across clinical trials is discussed, but is not a primary focus of this guidance. Selected principles and procedures related to data management or clinical trial monitoring activities are covered in other ICH guidances and are not addressed here.

This guidance should be of interest to individuals from a broad range of scientific disciplines. However, it is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in ICH E6. The role

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and responsibility of the trial statistician (see Glossary), in collaboration with other clinical trial professionals, is to ensure that statistical principles are applied appropriately in clinical trials supporting drug development. Thus, the trial statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance.

For each clinical trial contributing to a marketing application, all important details of its design and conduct and the principal features of its proposed statistical analysis should be clearly specified in a protocol written before the trial begins. The extent to which the procedures in the protocol are followed and the primary analysis is planned a priori will contribute to the degree of confidence in the final results and conclusions of the trial. The protocol and subsequent amendments should be approved by the responsible personnel, including the trial statistician. The trial statistician should ensure that the protocol and any amendments cover all relevant statistical issues clearly and accurately, using technical terminology as appropriate.

The principles outlined in this guidance are primarily relevant to clinical trials conducted in the later phases of development, many of which are confirmatory trials of efficacy. In addition to efficacy, confirmatory trials may have as their primary variable a safety variable (e.g., an adverse event, a clinical laboratory variable, or an electrocardiographic measure) or a pharmacodynamic or pharmacokinetic variable (as in a confirmatory bioequivalence trial). Furthermore, some confirmatory findings may be derived from data integrated across trials, and selected principles in this guidance are applicable in this situation. Finally, although the early phases of drug development consist mainly of clinical trials that are exploratory in nature, statistical principles are also relevant to these clinical trials. Hence, the substance of this document should be applied as far as possible to all phases of clinical development.

Many of the principles delineated in this guidance deal with minimizing bias (see Glossary) and maximizing precision. As used in this guidance, the term ''bias'' describes the systematic tendency of any factors associated with the design, conduct, analysis, and interpretation of the results of clinical trials to make the estimate of a treatment effect (see Glossary) deviate from its true value. It is important to identify potential sources of bias as completely as possible so that attempts to limit such bias may be made. The presence of bias may seriously compromise the ability to draw valid conclusions from clinical trials.

Some sources of bias arise from the design of the trial, for example an assignment of treatments such that subjects at lower risk are systematically assigned to one treatment. Other sources of bias arise during the conduct and analysis of a clinical trial. For example, protocol violations and exclusion of subjects from analysis based upon knowledge of subject outcomes are possible sources of bias that may affect the accurate assessment of the treatment effect. Because bias can occur in subtle or unknown ways and its effect is not measurable directly, it is important to evaluate the robustness of the results and primary conclusions of the trial. Robustness is a concept that refers to the sensitivity of the overall conclusions to various limitations of the data, assumptions, and analytic approaches to data analysis. Robustness implies that the treatment effect and primary conclusions of the trial are not substantially affected when analyses are carried out based on alternative assumptions or analytic approaches. The interpretation of statistical measures of uncertainty of the treatment effect and treatment comparisons should involve consideration of the potential contribution of bias to the p-value, confidence interval, or inference.

Because the predominant approaches to the design and analysis of clinical trials have been based on frequentist statistical methods, the guidance largely refers to the use of frequentist methods (see Glossary) when discussing hypothesis testing and/or confidence intervals. This should not be taken to imply that other approaches are not appropriate; the use of Bayesian (see Glossary) and other approaches may be considered when the reasons for their use are clear and when the resulting conclusions are sufficiently robust.

II. Considerations for Overall Clinical Development

2.1 Trial Context

2.1.1 Development Plan

The broad aim of the process of clinical development of a new drug is to find out whether there is a dose range and schedule at which the drug can be shown to be simultaneously safe and effective, to the extent that the risk-benefit relationship is acceptable. The particular subjects who may benefit from the drug, and the specific indications for its use, also need to be defined.

Satisfying these broad aims usually requires an ordered program of clinical trials, each with its own specific objectives (see ICH E8). This should be specified in a clinical plan, or a series of plans, with appropriate decision points and flexibility to allow modification as knowledge accumulates. A marketing application should clearly describe the main content of such plans, and the contribution made by each trial. Interpretation and assessment of the evidence from the total program of trials involves synthesis of the evidence from the individual trials (see section 7.2). This is facilitated by ensuring that common standards are adopted for a number of features of the trials, such as dictionaries of medical terms, definition and timing of the main measurements, handling of protocol deviations, and so on. A statistical summary, overview, or meta-analysis (see Glossary) may be informative when medical questions are addressed in more than one trial. Where possible, this should be envisaged in the plan so that the relevant trials are clearly identified and any necessary common features of their designs are specified in advance. Other major statistical issues (if any) that are expected to affect a number of trials in a common plan should be addressed in that plan.

2.1.2 Confirmatory Trial

A confirmatory trial is an adequately controlled trial in which the hypotheses are stated in advance and evaluated. As a rule, confirmatory trials are necessary to provide firm evidence of efficacy or safety. In such trials the key hypothesis of interest follows directly from the trial's primary objective, is always predefined, and is the hypothesis that is subsequently tested when the trial is complete. In a confirmatory trial, it is equally important to estimate with due precision the size of the effects attributable to the treatment of interest and to relate these effects to their clinical significance.

Confirmatory trials are intended to provide firm evidence in support of claims; hence adherence to protocols and standard operating procedures is particularly important. Unavoidable changes should be explained and documented, and their effect examined. A justification of the design of each such trial and of other important statistical aspects, such as the principal features of the planned analysis, should be set out in the protocol. Each trial should address only a limited number of questions.

Firm evidence in support of claims requires that the results of the confirmatory trials demonstrate that the investigational product under test has clinical benefits. The confirmatory trials should therefore be sufficient to answer each key clinical question relevant to the efficacy or safety claim clearly and definitively. In addition, it is important that the basis for generalization (see Glossary) to the intended patient population is understood and explained; this may also influence the number and type (e.g., specialist or general practitioner) of centers and/or trials needed. The results of the confirmatory trial(s) should be robust. In some circumstances, the weight of evidence from a single confirmatory trial may be sufficient.

2.1.3 Exploratory Trial

The rationale and design of confirmatory trials nearly always rests on earlier clinical work carried out in a series of exploratory studies. Like all clinical trials, these exploratory studies should have clear and precise objectives. However, in contrast to confirmatory trials, their objectives may not always lead to simple tests of predefined hypotheses. In addition, exploratory trials may sometimes require a more flexible approach to design so that changes can be made in response to accumulating results. Their analysis may entail data exploration. Tests of hypothesis may be carried out, but the choice of hypothesis may be data dependent. Such trials cannot be the basis of the formal proof of efficacy, although they may contribute to the total body of relevant evidence.

Any individual trial may have both confirmatory and exploratory aspects. For example, in most confirmatory trials the data are also subjected to exploratory analyses which serve as a basis for explaining or supporting their findings and for suggesting further hypotheses for later research. The protocol should make a clear distinction between the aspects of a trial which will be used for confirmatory proof and the aspects

which will provide data for exploratory analysis.

2.2 Scope of Trials

2.2.1 Population

In the earlier phases of drug development, the choice of subjects for a clinical trial may be heavily influenced by the wish to maximize the chance of observing specific clinical effects of interest. Hence they may come from a very narrow subgroup of the total patient population for which the drug may eventually be indicated. However, by the time the confirmatory trials are undertaken, the subjects in the trials should more closely mirror the target population. In these trials, it is generally helpful to relax the inclusion and exclusion criteria as much as possible within the target population while maintaining sufficient homogeneity to permit precise estimation of treatment effects. No individual clinical trial can be expected to be totally representative of future users because of the possible influences of geographical location, the time when it is conducted, the medical practices of the particular investigator(s) and clinics, and so on. However, the influence of such factors should be reduced wherever possible and subsequently discussed during the interpretation of the trial results.

2.2.2 Primary and Secondary Variables

The primary variable (''target'' variable, primary endpoint) should be the variable capable of providing the most clinically relevant and convincing evidence directly related to the primary objective of the trial. There should generally be only one primary variable. This will usually be an efficacy variable, because the primary objective of most confirmatory trials is to provide strong scientific evidence regarding efficacy. Safety/tolerability may sometimes be the primary variable, and will always be an important consideration. Measurements relating to quality of life and health economics are further potential primary variables. The selection of the primary variable should reflect the accepted norms and standards in the relevant field of research. The use of a reliable and validated variable with which experience has been gained either in earlier studies or in published literature is recommended. There should be sufficient evidence that the primary variable can provide a valid and reliable measure of some clinically relevant and important treatment benefit in the patient population described by the inclusion and exclusion criteria. The primary variable should generally be the one used when estimating the sample size (see section 3.5).

In many cases, the approach to assessing subject outcome may not be straightforward and should be carefully defined. For example, it is inadequate to specify mortality as a primary variable without further clarification; mortality may be assessed by comparing proportions alive at fixed points in time or by comparing overall distributions of survival times over a specified interval. Another common example is a recurring event; the measure of treatment effect may again be a simple dichotomous variable (any occurrence during a specified interval), time to first occurrence, rate of occurrence (events per time units of observation), and so on. The assessment of functional status over time in studying treatment for chronic disease presents other challenges in selection of the primary variable. There are many possible approaches, such as comparisons of the assessments done at the beginning and end of the interval of observation, comparisons of slopes calculated from all assessments throughout the interval, comparisons of the proportions of subjects exceeding or declining beyond a specified threshold, or comparisons based on methods for repeated measures data. To avoid multiplicity concerns arising from post hoc definitions, it is critical to specify in the protocol the precise definition of the primary variable as it will be used in the statistical analysis. In addition, the clinical relevance of the specific primary variable selected and the validity of the associated measurement procedures will generally need to be addressed and justified in the protocol.

The primary variable should be specified in the protocol, along with the rationale for its selection. Redefinition of the primary variable after unblinding will almost always be unacceptable, since the biases this introduces are difficult to assess. When the clinical effect defined by the primary objective is to be measured in more than one way, the protocol should identify one of the measurements as the primary variable on the basis of clinical relevance, importance, objectivity, and/or other relevant characteristics, whenever such selection is feasible.

Secondary variables are either supportive measurements related to the primary objective or measurements of effects related to the secondary objectives. Their predefinition in the protocol is also important, as well as an explanation of their relative importance and roles in interpretation of trial results. The number of secondary variables should be limited and should be related to the limited number of questions to be answered in the trial.

2.2.3 Composite Variables

If a single primary variable cannot be selected from multiple measurements associated with the primary objective, another useful strategy is to integrate or combine the multiple measurements into a single or ''composite'' variable, using a predefined algorithm. Indeed, the primary variable sometimes arises as a combination of multiple clinical measurements (e.g., the rating scales used in arthritis, psychiatric disorders, and elsewhere). This approach addresses the multiplicity problem without requiring adjustment to the Type I error. The method of combining the multiple measurements should be specified in the protocol, and an interpretation of the resulting scale should be provided in terms of the size of a clinically relevant benefit. When a composite variable is used as a primary variable, the components of this variable may sometimes be analyzed separately, where clinically meaningful and validated. When a rating scale is used as a primary variable, it is especially important to address factors such as content validity (see Glossary), inter- and intrarater reliability (see Glossary), and responsiveness for detecting changes in the severity of disease.

2.2.4 Global Assessment Variables

In some cases, ''global assessment'' variables (see Glossary) are developed to measure the overall safety, overall efficacy, and/or overall usefulness of a treatment. This type of variable integrates objective variables and the investigator's overall impression about the state or change in the state of the subject, and is usually a scale of ordered categorical ratings. Global assessments of overall efficacy are well established in some therapeutic areas, such as neurology and psychiatry.

Global assessment variables generally have a subjective component. When a global assessment variable is used as a primary or secondary variable, fuller details of the scale should be included in the protocol with respect to:

(1) The relevance of the scale to the primary objective of the trial;

(2) The basis for the validity and reliability of the scale;

(3) How to utilize the data collected on an individual subject to assign him/her to a unique category of the scale;

(4) How to assign subjects with missing data to a unique category of the scale, or otherwise evaluate them.

If objective variables are considered by the investigator when making a global assessment, then those objective variables should be considered as additional primary or, at least, important secondary variables.

Global assessment of usefulness integrates components of both benefit and risk and reflects the decisionmaking process of the treating physician, who must weigh benefit and risk in making product use decisions. A problem with global usefulness variables is that their use could in some cases lead to the result of two products being declared equivalent despite having very different profiles of beneficial and adverse effects. For example, judging the global usefulness of a treatment as equivalent or superior to an alternative may mask the fact that it has little or no efficacy but fewer adverse effects. Therefore, it is not advisable to use a global usefulness variable as a primary variable. If global usefulness is specified as primary, it is important to consider specific efficacy and safety outcomes separately as additional primary variables.

2.2.5 Multiple Primary Variables

It may sometimes be desirable to use more than one primary variable, each of which (or a subset of which) could be sufficient to cover the range of effects of the therapies. The planned manner of interpretation of this type of evidence should be carefully spelled out. It should be clear whether an impact on any of the variables, some minimum number of them, or all of them, would be considered necessary to achieve the trial objectives. The primary hypothesis or hypotheses and parameters of interest (e.g., mean, percentage, distribution) should be clearly stated with respect to the primary variables identified, and the approach to statistical inference described. The effect on the Type I error should be explained because of the potential for multiplicity problems (see section 5.6);

the method of controlling Type I error should be given in the protocol. The extent of intercorrelation among the proposed primary variables may be considered in evaluating the impact on Type I error. If the purpose of the trial is to demonstrate effects on all of the designated primary variables, then there is no need for adjustment of the Type I error, but the impact on Type II error and sample size should be carefully considered.

2.2.6 Surrogate Variables

When direct assessment of the clinical benefit to the subject through observing actual clinical efficacy is not practical, indirect criteria (surrogate variables—see Glossary) may be considered. Commonly accepted surrogate variables are used in a number of indications where they are believed to be reliable predictors of clinical benefit. There are two principal concerns with the introduction of any proposed surrogate variable. First, it may not be a true predictor of the clinical outcome of interest. For example, it may measure treatment activity associated with one specific pharmacological mechanism, but may not provide full information on the range of actions and ultimate effects of the treatment, whether positive or negative. There have been many instances where treatments showing a highly positive effect on a proposed surrogate have ultimately been shown to be detrimental to the subjects' clinical outcome; conversely, there are cases of treatments conferring clinical benefit without measurable impact on proposed surrogates. Secondly, proposed surrogate variables may not yield a quantitative measure of clinical benefit that can be weighed directly against adverse effects. Statistical criteria for validating surrogate variables have been proposed but the experience with their use is relatively limited. In practice, the strength of the evidence for surrogacy depends upon (i) the biological plausibility of the relationship, (ii) the demonstration in epidemiological studies of the prognostic value of the surrogate for the clinical outcome, and (iii) evidence from clinical trials that treatment effects on the surrogate correspond to effects on the clinical outcome. Relationships between clinical and surrogate variables for one product do not necessarily apply to a product with a different mode of action for treating the same disease.

2.2.7 Categorized Variables

Dichotomization or other categorization of continuous or ordinal variables may sometimes be desirable. Criteria of ''success'' and ''response'' are common examples of dichotomies that should be specified precisely in terms of, for example, a minimum percentage improvement (relative to baseline) in a continuous variable or a ranking categorized as at or above some threshold level (e.g., ''good'') on an ordinal rating scale. The reduction of diastolic blood pressure below 90 mmHg is a common dichotomization. Categorizations are most useful when they have clear clinical relevance. The criteria for categorization should be predefined and specified in the protocol, as knowledge of trial results could easily bias the choice of such criteria. Because categorization normally implies a loss of information, a consequence will be a loss of power in the analysis; this should be accounted for in the sample size calculation.

2.3 Design Techniques to Avoid Bias

The most important design techniques for avoiding bias in clinical trials are blinding and randomization, and these should be normal features of most controlled clinical trials intended to be included in a marketing application. Most such trials follow a double-blind approach in which treatments are prepacked in accordance with a suitable randomization schedule, and supplied to the trial center(s) labeled only with the subject number and the treatment period, so that no one involved in the conduct of the trial is aware of the specific treatment allocated to any particular subject, not even as a code letter. This approach will be assumed in section 2.3.1 and most of section 2.3.2, exceptions being considered at the end.

Bias can also be reduced at the design stage by specifying procedures in the protocol aimed at minimizing any anticipated irregularities in trial conduct that might impair a satisfactory analysis, including various types of protocol violations, withdrawals and missing values. The protocol should consider ways both to reduce the frequency of such problems and to handle the problems that do occur in the analysis of data.

2.3.1 Blinding

Blinding or masking is intended to limit the occurrence of conscious and unconscious bias in the conduct and interpretation of a clinical trial arising from the influence that the knowledge of treatment may have on the recruitment and allocation of subjects, their subsequent care, the attitudes of subjects to the treatments, the assessment of end-points, the handling of withdrawals, the exclusion of data from analysis, and so on. The essential aim is to prevent identification of the treatments until all such opportunities for bias have passed.

A double-blind trial is one in which neither the subject nor any of the investigator or sponsor staff involved in the treatment or clinical evaluation of the subjects are aware of the treatment received. This includes anyone determining subject eligibility, evaluating endpoints, or assessing compliance with the protocol. This level of blinding is maintained throughout the conduct of the trial, and only when the data are cleaned to an acceptable level of quality will appropriate personnel be unblinded. If any of the sponsor staff who are not involved in the treatment or clinical evaluation of the subjects are required to be unblinded to the treatment code (e.g., bioanalytical scientists, auditors, those involved in serious adverse event reporting), the sponsor should have adequate standard operating procedures to guard against inappropriate dissemination of treatment codes. In a single-blind trial the investigator and/or his staff are aware of the treatment but the subject is not, or vice versa. In an open-label trial the identity of treatment is known to all. The double-blind trial is the optimal approach. This requires that the treatments to be applied during the trial cannot be distinguished (by appearance, taste, etc.) either before or during administration, and that the blind is maintained appropriately during the whole trial.

Difficulties in achieving the double-blind ideal can arise: The treatments may be of a completely different nature, for example, surgery and drug therapy; two drugs may have different formulations and, although they could be made indistinguishable by the use of capsules, changing the formulation might also change the pharmacokinetic and/or pharmacodynamic properties and hence necessitate that bioequivalence of the formulations be established; the daily pattern of administration of two treatments may differ. One way of achieving double-blind conditions under these circumstances is to use a ''double-dummy'' (see Glossary) technique. This technique may sometimes force an administration scheme that is sufficiently unusual to influence adversely the motivation and compliance of the subjects. Ethical difficulties may also interfere with its use when, for example, it entails dummy operative procedures. Nevertheless, extensive efforts should be made to overcome these difficulties.

The double-blind nature of some clinical trials may be partially compromised by apparent treatment induced effects. In such cases, blinding may be improved by blinding investigators and relevant sponsor staff to certain test results (e.g., selected clinical laboratory measures). Similar approaches (see below) to minimizing bias in open-label trials should be considered in trials where unique or specific treatment effects may lead to unblinding individual patients.

If a double-blind trial is not feasible, then the single-blind option should be considered. In some cases only an open-label trial is practically or ethically possible. Single-blind and open-label trials provide additional flexibility, but it is particularly important that the investigator's knowledge of the next treatment should not influence the decision to enter the subject; this decision should precede knowledge of the randomized treatment. For these trials, consideration should be given to the use of a centralized randomization method, such as telephone randomization, to administer the assignment of randomized treatment. In addition, clinical assessments should be made by medical staff who are not involved in treating the subjects and who remain blind to treatment. In single-blind or open-label trials every effort should be made to minimize the various known sources of bias and primary variables should be as objective as possible. The reasons for the degree of blinding adopted, as well as steps taken to minimize bias by other means, should be explained in the protocol. For example, the sponsor should have adequate standard operating procedures to ensure that access to the treatment code is appropriately restricted during the process of cleaning the database prior to its release for analysis.

Breaking the blind (for a single subject) should be considered only when knowledge of the treatment assignment is deemed essential by the subject's physician for the subject's care. Any intentional or unintentional breaking of the blind should be reported and explained at the end of the trial,

irrespective of the reason for its occurrence. The procedure and timing for revealing the treatment assignments should be documented.

In this document, the blind review (see Glossary) of data refers to the checking of data during the period of time between trial completion (the last observation on the last subject) and the breaking of the blind.

2.3.2 Randomization

Randomization introduces a deliberate element of chance into the assignment of treatments to subjects in a clinical trial. During subsequent analysis of the trial data, it provides a sound statistical basis for the quantitative evaluation of the evidence relating to treatment effects. It also tends to produce treatment groups in which the distributions of prognostic factors, known and unknown, are similar. In combination with blinding, randomization helps to avoid possible bias in the selection and allocation of subjects arising from the predictability of treatment assignments.

The randomization schedule of a clinical trial documents the random allocation of treatments to subjects. In the simplest situation it is a sequential list of treatments (or treatment sequences in a crossover trial) or corresponding codes by subject number. The logistics of some trials, such as those with a screening phase, may make matters more complicated, but the unique preplanned assignment of treatment, or treatment sequence, to subject should be clear. Different trial designs will necessitate different procedures for generating randomization schedules. The randomization schedule should be reproducible (if the need arises).

Although unrestricted randomization is an acceptable approach, some advantages can generally be gained by randomizing subjects in blocks. This helps to increase the comparability of the treatment groups, particularly when subject characteristics may change over time, as a result, for example, of changes in recruitment policy. It also provides a better guarantee that the treatment groups will be of nearly equal size. In crossover trials, it provides the means of obtaining balanced designs with their greater efficiency and easier interpretation. Care should be taken to choose block lengths that are sufficiently short to limit possible imbalance, but that are long enough to avoid predictability towards the end of the sequence in a block. Investigators and other relevant staff should generally be blind to the block length; the use of two or more block lengths, randomly selected for each block, can achieve the same purpose. (Theoretically, in a double-blind trial predictability does not matter, but the pharmacological effects of drugs may provide the opportunity for intelligent guesswork.)

In multicenter trials (see Glossary), the randomization procedures should be organized centrally. It is advisable to have a separate random scheme for each center, i.e., to stratify by center or to allocate several whole blocks to each center. More generally, stratification by important prognostic factors measured at baseline (e.g., severity of disease, age, sex) may sometimes be valuable in order to promote balanced allocation within strata; this has greater potential benefit in small trials. The use of more than two or three stratification factors is rarely necessary, is less successful at achieving balance, and is logistically troublesome. The use of a dynamic allocation procedure (see below) may help to achieve balance across a number of stratification factors simultaneously, provided the rest of the trial procedures can be adjusted to accommodate an approach of this type. Factors on which randomization has been stratified should be accounted for later in the analysis.

The next subject to be randomized into a trial should always receive the treatment corresponding to the next free number in the appropriate randomization schedule (in the respective stratum, if randomization is stratified). The appropriate number and associated treatment for the next subject should only be allocated when entry of that subject to the randomized part of the trial has been confirmed. Details of the randomization that facilitate predictability (e.g., block length) should not be contained in the trial protocol. The randomization schedule itself should be filed securely by the sponsor or an independent party in a manner that ensures that blindness is properly maintained throughout the trial. Access to the randomization schedule during the trial should take into account the possibility that, in an emergency, the blind may have to be broken for any subject. The procedure to be followed, the necessary documentation, and the subsequent treatment and assessment of the subject should all be described in the protocol.

Dynamic allocation is an alternative procedure in which the allocation of treatment to a subject is influenced by the current balance of allocated treatments and, in a stratified trial, by the stratum to which the subject belongs and the balance within that stratum. Deterministic dynamic allocation procedures should be avoided and an appropriate element of randomization should be incorporated for each treatment allocation. Every effort should be made to retain the double-blind status of the trial. For example, knowledge of the treatment code may be restricted to a central trial office from where the dynamic allocation is controlled, generally through telephone contact. This in turn permits additional checks of eligibility criteria and establishes entry into the trial, features that can be valuable in certain types of multicenter trials. The usual system of prepacking and labeling drug supplies for double-blind trials can then be followed, but the order of their use is no longer sequential. It is desirable to use appropriate computer algorithms to keep personnel at the central trial office blind to the treatment code. The complexity of the logistics and potential impact on the analysis should be carefully evaluated when considering dynamic allocation.

III. Trial Design Considerations

3.1 Design Configuration

3.1.1 Parallel Group Design

The most common clinical trial design for confirmatory trials is the parallel group design in which subjects are randomized to one of two or more arms, each arm being allocated a different treatment. These treatments will include the investigational product at one or more doses, and one or more control treatments, such as placebo and/or an active comparator. The assumptions underlying this design are less complex than for most other designs. However, as with other designs, there may be additional features of the trial that complicate the analysis and interpretation (e.g., covariates, repeated measurements over time, interactions between design factors, protocol violations, dropouts (see Glossary), and withdrawals).

3.1.2 Crossover Design

In the crossover design, each subject is randomized to a sequence of two or more treatments and hence acts as his own control for treatment comparisons. This simple maneuver is attractive primarily because it reduces the number of subjects and usually the number of assessments needed to achieve a specific power, sometimes to a marked extent. In the simplest 2 2 crossover design, each subject receives each of two treatments in randomized order in two successive treatment periods, often separated by a washout period. The most common extension of this entails comparing n(≤2) treatments in n periods, each subject receiving all n treatments. Numerous variations exist, such as designs in which each subject receives a subset of n(≤2) treatments, or designs in which treatments are repeated within a subject.

Crossover designs have a number of problems that can invalidate their results. The chief difficulty concerns carryover, that is, the residual influence of treatments in subsequent treatment periods. In an additive model, the effect of unequal carryover will be to bias direct treatment comparisons. In the 2 2 design, the carryover effect cannot be statistically distinguished from the interaction between treatment and period and the test for either of these effects lacks power because the corresponding contrast is ''between subject.'' This problem is less acute in higher order designs, but cannot be entirely dismissed.

When the crossover design is used, it is therefore important to avoid carryover. This is best done by selective and careful use of the design on the basis of adequate knowledge of both the disease area and the new medication. The disease under study should be chronic and stable. The relevant effects of the medication should develop fully within the treatment period. The washout periods should be sufficiently long for complete reversibility of drug effect. The fact that these conditions are likely to be met should be established in advance of the trial by means of prior information and data.

There are additional problems that need careful attention in crossover trials. The most notable of these are the complications of analysis and interpretation arising from the loss of subjects. Also, the potential for carryover leads to difficulties in assigning adverse events that occur in later treatment periods to the appropriate treatment. These and other issues are described in ICH E4. The crossover design should generally be restricted to situations where losses of

subjects from the trial are expected to be small.

A common, and generally satisfactory, use of the 2 2 crossover design is to demonstrate the bioequivalence of two formulations of the same medication. In this particular application in healthy volunteers, carryover effects on the relevant pharmacokinetic variable are most unlikely to occur if the wash-out time between the two periods is sufficiently long. However, it is still important to check this assumption during analysis on the basis of the data obtained, for example, by demonstrating that no drug is detectable at the start of each period.

3.1.3 Factorial Designs

In a factorial design, two or more treatments are evaluated simultaneously through the use of varying combinations of the treatments. The simplest example is the 2 2 factorial design in which subjects are randomly allocated to one of the four possible combinations of two treatments, A and B. These are: A alone; B alone; both A and B; neither A nor B. In many cases, this design is used for the specific purpose of examining the interaction of A and B. The statistical test of interaction may lack power to detect an interaction if the sample size was calculated based on the test for main effects. This consideration is important when this design is used for examining the joint effects of A and B, in particular, if the treatments are likely to be used together.

Another important use of the factorial design is to establish the dose-response characteristics of the simultaneous use of treatments C and D, especially when the efficacy of each monotherapy has been established at some dose in prior trials. A number, m, of doses of C is selected, usually including a zero dose (placebo), and a similar number, n, of doses of D. The full design then consists of m n treatment groups, each receiving a different combination of doses of C and D. The resulting estimate of the response surface may then be used to help identify an appropriate combination of doses of C and D for clinical use (see ICH E4).

In some cases, the 2 2 design may be used to make efficient use of clinical trial subjects by evaluating the efficacy of the two treatments with the same number of subjects as would be required to evaluate the efficacy of either one alone. This strategy has proved to be particularly valuable for very large mortality trials. The efficiency and validity of this approach depends upon the absence of interaction between treatments A and B so that the effects of A and B on the primary efficacy variables follow an additive model. Hence the effect of A is virtually identical whether or not it is additional to the effect of B. As for the crossover trial, evidence that this condition is likely to be met should be established in advance of the trial by means of prior information and data.

3.2 Multicenter Trials

Multicenter trials are carried out for two main reasons. First, a multicenter trial is an accepted way of evaluating a new medication more efficiently. Under some circumstances, it may present the only practical means of accruing sufficient subjects to satisfy the trial objective within a reasonable timeframe. Multicenter trials of this nature may, in principle, be carried out at any stage of clinical development. They may have several centers with a large number of subjects per center or, in the case of a rare disease, they may have a large number of centers with very few subjects per center.

Second, a trial may be designed as a multicenter (and multi-investigator) trial primarily to provide a better basis for the subsequent generalization of its findings. This arises from the possibility of recruiting the subjects from a wider population and of administering the medication in a broader range of clinical settings, thus presenting an experimental situation that is more typical of future use. In this case, the involvement of a number of investigators also gives the potential for a wider range of clinical judgment concerning the value of the medication. Such a trial would be a confirmatory trial in the later phases of drug development and would be likely to involve a large number of investigators and centers. It might sometimes be conducted in a number of different countries to facilitate generalizability (see Glossary) even further.

If a multicenter trial is to be meaningfully interpreted and extrapolated, then the manner in which the protocol is implemented should be clear and similar at all centers. Furthermore, the usual sample size and power calculations depend upon the assumption that the differences between the compared treatments in the centers are unbiased estimates of the same quantity. It is important to design the common protocol and to conduct the trial with this background in mind. Procedures should be standardized as completely as possible. Variation of evaluation criteria and schemes can be reduced by investigator meetings, by the training of personnel in advance of the trial, and by careful monitoring during the trial. Good design should generally aim to achieve the same distribution of subjects to treatments within each center and good management should maintain this design objective. Trials that avoid excessive variation in the numbers of subjects per center and trials that avoid a few very small centers have advantages if it is later found necessary to take into account the heterogeneity of the treatment effect from center to center, because they reduce the differences between different weighted estimates of the treatment effect. (This point does not apply to trials in which all centers are very small and in which center does not feature in the analysis.) Failure to take these precautions, combined with doubts about the homogeneity of the results, may, in severe cases, reduce the value of a multicenter trial to such a degree that it cannot be regarded as giving convincing evidence for the sponsor's claims.

In the simplest multicenter trial, each investigator will be responsible for the subjects recruited at one hospital, so that ''center'' is identified uniquely by either investigator or hospital. In many trials, however, the situation is more complex. One investigator may recruit subjects from several hospitals; one investigator may represent a team of clinicians (subinvestigators) who all recruit subjects from their own clinics at one hospital or at several associated hospitals. Whenever there is room for doubt about the definition of center in a statistical model, the statistical section of the protocol (see section 5.1) should clearly define the term (e.g., by investigator, location or region) in the context of the particular trial. In most instances, centers can be satisfactorily defined through the investigators. (ICH E6 provides relevant guidance in this respect.) In cases of doubt, the aim should be to define centers to achieve homogeneity in the important factors affecting the measurements of the primary variables and the influence of the treatments. Any rules for combining centers in the analysis should be justified and specified prospectively in the protocol where possible, but in any case decisions concerning this approach should always be taken blind to treatment, for example, at the time of the blind review.

The statistical model to be adopted for the estimation and testing of treatment effects should be described in the protocol. The main treatment effect may be investigated first using a model that allows for center differences, but does not include a term for treatment-by-center interaction. If the treatment effect is homogeneous across centers, the routine inclusion of interaction terms in the model reduces the efficiency of the test for the main effects. In the presence of true heterogeneity of treatment effects, the interpretation of the main treatment effect is controversial.

In some trials, for example, some large mortality trials with very few subjects per center, there may be no reason to expect the centers to have any influence on the primary or secondary variables because they are unlikely to represent influences of clinical importance. In other trials, it may be recognized from the start that the limited numbers of subjects per center will make it impracticable to include the center effects in the statistical model. In these cases, it is not considered appropriate to include a term for center in the model, and it is not necessary to stratify the randomization by center in this situation.

If positive treatment effects are found in a trial with appreciable numbers of subjects per center, there should generally be an exploration of the heterogeneity of treatment effects across centers, as this may affect the generalizability of the conclusions. Marked heterogeneity may be identified by graphical display of the results of individual centers or by analytical methods, such as a significance test of the treatment-by-center interaction. When using such a statistical significance test, it is important to recognize that this generally has low power in a trial designed to detect the main effect of treatment.

If heterogeneity of treatment effects is found, this should be interpreted with care, and vigorous attempts should be made to find an explanation in terms of other features of trial management or subject characteristics. Such an explanation will usually suggest appropriate further analysis and interpretation. In the absence of an explanation, heterogeneity of treatment effect, as evidenced, for example, by marked quantitative interactions (see Glossary) implies that alternative estimates of the

treatment effect, giving different weights to the centers, may be needed to substantiate the robustness of the estimates of treatment effect. It is even more important to understand the basis of any heterogeneity characterized by marked qualitative interactions (see Glossary), and failure to find an explanation may necessitate further clinical trials before the treatment effect can be reliably predicted.

Up to this point, the discussion of multicenter trials has been based on the use of fixed effect models. Mixed models may also be used to explore the heterogeneity of the treatment effect. These models consider center and treatment-by-center effects to be random and are especially relevant when the number of sites is large.

3.3 Type of Comparison

3.3.1 Trials to Show Superiority

Scientifically, efficacy is most convincingly established by demonstrating superiority to placebo in a placebo-controlled trial, by showing superiority to an active control treatment, or by demonstrating a dose-response relationship. This type of trial is referred to as a ''superiority'' trial (see Glossary). In this guidance superiority trials are generally assumed, unless explicitly stated otherwise.

For serious illnesses, when a therapeutic treatment that has been shown to be efficacious by superiority trial(s) exists, a placebo-controlled trial may be considered unethical. In that case the scientifically sound use of an active treatment as a control should be considered. The appropriateness of placebo control versus active control should be considered on a trial-by-trial basis.

3.3.2 Trials to Show Equivalence or Noninferiority

In some cases, an investigational product is compared to a reference treatment without the objective of showing superiority. This type of trial is divided into two major categories according to its objective; one is an ''equivalence'' trial (see Glossary) and the other is a ''noninferiority'' trial (see Glossary).

Bioequivalence trials fall into the former category. In some situations, clinical equivalence trials are also undertaken for other regulatory reasons such as demonstrating the clinical equivalence of a generic product to the marketed product when the compound is not absorbed and therefore not present in the blood stream.

Many active control trials are designed to show that the efficacy of an investigational product is no worse than that of the active comparator and, hence, fall into the latter category. Another possibility is a trial in which multiple doses of the investigational drug are compared with the recommended dose or multiple doses of the standard drug. The purpose of this design is simultaneously to show a dose-response relationship for the investigational product and to compare the investigational product with the active control.

Active control equivalence or noninferiority trials may also incorporate a placebo, thus pursuing multiple goals in one trial. For example, they may establish superiority to placebo and hence validate the trial design and simultaneously evaluate the degree of similarity of efficacy and safety to the active comparator. There are well-known difficulties associated with the use of the active control equivalence (or noninferiority) trials that do not incorporate a placebo or do not use multiple doses of the new drug. These relate to the implicit lack of any measure of internal validity (in contrast to superiority trials), thus making external validation necessary. The equivalence (or noninferiority) trial is not conservative in nature, so that many flaws in the design or conduct of the trial will tend to bias the results towards a conclusion of equivalence. For these reasons, the design features of such trials should receive special attention and their conduct needs special care. For example, it is especially important to minimize the incidence of violations of the entry criteria, noncompliance, withdrawals, losses to follow-up, missing data, and other deviations from the protocol, and also to minimize their impact on the subsequent analyses.

Active comparators should be chosen with care. An example of a suitable active comparator would be a widely used therapy whose efficacy in the relevant indication has been clearly established and quantified in well-designed and well-documented superiority trial(s) and that can be reliably expected to exhibit similar efficacy in the contemplated active control trial. To this end, the new trial should have the same important design features (primary variables, the dose of the active comparator, eligibility criteria, and so on) as the previously conducted superiority trials in which the active comparator clearly demonstrated clinically relevant efficacy, taking into account advances in medical or statistical practice relevant to the new trial.

It is vital that the protocol of a trial designed to demonstrate equivalence or noninferiority contain a clear statement that this is its explicit intention. An equivalence margin should be specified in the protocol; this margin is the largest difference that can be judged as being clinically acceptable and should be smaller than differences observed in superiority trials of the active comparator. For the active control equivalence trial, both the upper and the lower equivalence margins are needed, while only the lower margin is needed for the active control noninferiority trial. The choice of equivalence margins should be justified clinically.

Statistical analysis is generally based on the use of confidence intervals (see section 5.5). For equivalence trials, two-sided confidence intervals should be used. Equivalence is inferred when the entire confidence interval falls within the equivalence margins. Operationally, this is equivalent to the method of using two simultaneous one-sided tests to test the (composite) null hypothesis that the treatment difference is outside the equivalence margins versus the (composite) alternative hypothesis that the treatment difference is within the margins. Because the two null hypotheses are disjoint, the Type I error is appropriately controlled. For noninferiority trials, a one-sided interval should be used. The confidence interval approach has a one-sided hypothesis test counterpart for testing the null hypothesis that the treatment difference (investigational product minus control) is equal to the lower equivalence margin versus the alternative that the treatment difference is greater than the lower equivalence margin. The choice of Type I error should be a consideration separate from the use of a one-sided or two-sided procedure. Sample size calculations should be based on these methods (see section 3.5).

Concluding equivalence or noninferiority based on observing a nonsignificant test result of the null hypothesis that there is no difference between the investigational product and the active comparator is considered inappropriate.

There are also special issues in the choice of analysis sets. Subjects who withdraw or drop out of the treatment group or the comparator group will tend to have a lack of response; hence the results of using the full analysis set (see Glossary) may be biased toward demonstrating equivalence (see section 5.2.3).

3.3.3 Trials to Show Dose-Response Relationship

How response is related to the dose of a new investigational product is a question to which answers may be obtained in all phases of development and by a variety of approaches (see ICH E4). Dose-response trials may serve a number of objectives, among which the following are of particular importance: The confirmation of efficacy; the investigation of the shape and location of the dose-response curve; the estimation of an appropriate starting dose; the identification of optimal strategies for individual dose adjustments; the determination of a maximal dose beyond which additional benefit would be unlikely to occur. These objectives should be addressed using the data collected at a number of doses under investigation, including a placebo (zero dose) wherever appropriate. For this purpose, the application of procedures to estimate the relationship between dose and response, including the construction of confidence intervals and the use of graphical methods, is as important as the use of statistical tests. The hypothesis tests that are used may need to be tailored to the natural ordering of doses or to particular questions regarding the shape of the dose-response curve (e.g., monotonicity). The details of the planned statistical procedures should be given in the protocol.

3.4 Group Sequential Designs

Group sequential designs are used to facilitate the conduct of interim analysis (see section 4.5 and Glossary). While group sequential designs are not the only acceptable types of designs permitting interim analysis, they are the most commonly applied because it is more practicable to assess grouped subject outcomes at periodic intervals during the trial than on a continuous basis as data from each subject become available. The statistical methods should be fully specified in advance of the availability of information on treatment outcomes and subject treatment assignments (i.e., blind breaking, see section 4.5). An

independent data monitoring committee (IDMC) (see Glossary) may be used to review or to conduct the interim analysis of data arising from a group sequential design (see section 4.6). While the design has been most widely and successfully used in large, long-term trials of mortality or major nonfatal endpoints, its use is growing in other circumstances. In particular, it is recognized that safety must be monitored in all trials; therefore, the need for formal procedures to cover early stopping for safety reasons should always be considered.

3.5 Sample Size

The number of subjects in a clinical trial should always be large enough to provide a reliable answer to the questions addressed. This number is usually determined by the primary objective of the trial. If the sample size is determined on some other basis, then this should be made clear and justified. For example, a trial sized on the basis of safety questions or requirements or important secondary objectives may need larger numbers of subjects than a trial sized on the basis of the primary efficacy question (see, for example, ICH E1A).

Using the usual method for determining the appropriate sample size, the following items should be specified: A primary variable; the test statistic; the null hypothesis; the alternative (''working'') hypothesis at the chosen dose(s) (embodying consideration of the treatment difference to be detected or rejected at the dose and in the subject population selected); the probability of erroneously rejecting the null hypothesis (the Type I error) and the probability of erroneously failing to reject the null hypothesis (the Type II error); as well as the approach to dealing with treatment withdrawals and protocol violations. In some instances, the event rate is of primary interest for evaluating power, and assumptions should be made to extrapolate from the required number of events to the eventual sample size for the trial.

The method by which the sample size is calculated should be given in the protocol, together with the estimates of any quantities used in the calculations (such as variances, mean values, response rates, event rates, difference to be detected). The basis of these estimates should also be given. It is important to investigate the sensitivity of the sample size estimate to a variety of deviations from these assumptions and this may be facilitated by providing a range of sample sizes appropriate for a reasonable range of deviations from assumptions. In confirmatory trials, assumptions should normally be based on published data or on the results of earlier trials. The treatment difference to be detected may be based on a judgment concerning the minimal effect which has clinical relevance in the management of patients or on a judgment concerning the anticipated effect of the new treatment, where this is larger. Conventionally, the probability of Type I error is set at 5 percent or less or as dictated by any adjustments made necessary for multiplicity considerations; the precise choice may be influenced by the prior plausibility of the hypothesis under test and the desired impact of the results. The probability of Type II error is conventionally set at 10 percent to 20 percent. It is in the sponsor's interest to keep this figure as low as feasible, especially in the case of trials that are difficult or impossible to repeat. Alternative values to the conventional levels of Type I and Type II error may be acceptable or even preferable in some cases.

Sample size calculations should refer to the number of subjects required for the primary analysis. If this is the ''full analysis set,'' estimates of the effect size may need to be reduced compared to the per protocol set (see Glossary). This is to allow for the dilution of the treatment effect arising from the inclusion of data from patients who have withdrawn from treatment or whose compliance is poor. The assumptions about variability may also need to be revised.

The sample size of an equivalence trial or a noninferiority trial (see section 3.3.2) should normally be based on the objective of obtaining a confidence interval for the treatment difference that shows that the treatments differ at most by a clinically acceptable difference. When the power of an equivalence trial is assessed at a true difference of zero, then the sample size necessary to achieve this power is underestimated if the true difference is not zero. When the power of a noninferiority trial is assessed at a zero difference, then the sample size needed to achieve that power will be underestimated if the effect of the investigational product is less than that of the active control. The choice of a ''clinically acceptable'' difference needs justification with respect to its meaning for future patients, and may be smaller than the ''clinically relevant'' difference referred to above in the context of superiority trials designed to establish that a difference exists.

The exact sample size in a group sequential trial cannot be fixed in advance because it depends upon the play of chance in combination with the chosen stopping guideline and the true treatment difference. The design of the stopping guideline should take into account the consequent distribution of the sample size, usually embodied in the expected and maximum sample sizes.

When event rates are lower than anticipated or variability is larger than expected, methods for sample size reestimation are available without unblinding data or making treatment comparisons (see section 4.4).

3.6 Data Capture and Processing

The collection of data and transfer of data from the investigator to the sponsor can take place through a variety of media, including paper case record forms, remote site monitoring systems, medical computer systems, and electronic transfer. Whatever data capture instrument is used, the form and content of the information collected should be in full accordance with the protocol and should be established in advance of the conduct of the clinical trial. It should focus on the data necessary to implement the planned analysis, including the context information (such as timing assessments relative to dosing) necessary to confirm protocol compliance or identify important protocol deviations. ''Missing values'' should be distinguishable from the ''value zero'' or ''characteristic absent.''

The process of data capture, through to database finalization, should be carried out in accordance with good clinical practice (GCP) (see ICH E6, section 5). Specifically, timely and reliable processes for recording data and rectifying errors and omissions are necessary to ensure delivery of a quality database and the achievement of the trial objectives through the implementation of the planned analysis.

IV. Trial Conduct Considerations

4.1 Trial Monitoring and Interim Analysis

Careful conduct of a clinical trial according to the protocol has a major impact on the credibility of the results (see ICH E6). Careful monitoring can ensure that difficulties are noticed early and their occurrence or recurrence minimized.

There are two distinct types of monitoring that generally characterize confirmatory clinical trials sponsored by the pharmaceutical industry. One type of monitoring concerns the oversight of the quality of the trial, while the other type involves breaking the blind to make treatment comparisons (i.e., interim analysis). Both types of trial monitoring, in addition to entailing different staff responsibilities, involve access to different types of trial data and information, and thus different principles apply for the control of potential statistical and operational bias.

For the purpose of overseeing the quality of the trial, the checks involved in trial monitoring may include whether the protocol is being followed, the acceptability of data being accrued, the success of planned accrual targets, the appropriateness of the design assumptions, success in keeping patients in the trials, and so on (see sections 4.2 to 4.4). This type of monitoring does not require access to information on comparative treatment effects nor unblinding of data and, therefore, has no impact on Type I error. The monitoring of a trial for this purpose is the responsibility of the sponsor (see ICH E6) and can be carried out by the sponsor or an independent group selected by the sponsor. The period for this type of monitoring usually starts with the selection of the trial sites and ends with the collection and cleaning of the last subject's data.

The other type of trial monitoring (interim analysis) involves the accruing of comparative treatment results. Interim analysis requires unblinded (i.e., key breaking) access to treatment group assignment (actual treatment assignment or identification of group assignment) and comparative treatment group summary information. Therefore, the protocol (or appropriate amendments prior to a first analysis) should contain statistical plans for the interim analysis to prevent certain types of bias. This is discussed in sections 4.5 and 4.6.

4.2 Changes in Inclusion and Exclusion Criteria

Inclusion and exclusion criteria should remain constant, as specified in the protocol, throughout the period of subject recruitment.

Changes may occasionally be appropriate, for example, in long-term trials, where growing medical knowledge either from outside the trial or from interim analyses may suggest a change of entry criteria. Changes may also result from the discovery by monitoring staff that regular violations of the entry criteria are occurring or that seriously low recruitment rates are due to over-restrictive criteria. Changes should be made without breaking the blind and should always be described by a protocol amendment. This amendment should cover any statistical consequences, such as sample size adjustments arising from different event rates, or modifications to the planned analysis, such as stratifying the analysis according to modified inclusion/exclusion criteria.

4.3 Accrual Rates

In trials with a long time-scale for the accrual of subjects, the rate of accrual should be monitored. If it falls appreciably below the projected level, the reasons should be identified and remedial actions taken to protect the power of the trial and alleviate concerns about selective entry and other aspects of quality. In a multicenter trial, these considerations apply to the individual centers.

4.4 Sample Size Adjustment

In long-term trials there will usually be an opportunity to check the assumptions which underlie the original design and sample size calculations. This may be particularly important if the trial specifications have been made on preliminary and/or uncertain information. An interim check conducted on the blinded data may reveal that overall response variances, event rates or survival experience are not as anticipated. A revised sample size may then be calculated using suitably modified assumptions, and should be justified and documented in a protocol amendment and in the clinical study report. The steps taken to preserve blindness and the consequences, if any, for the Type I error and the width of confidence intervals should be explained. The potential need for re-estimation of the sample size should be envisaged in the protocol whenever possible (see section 3.5).

4.5 Interim Analysis and Early Stopping

An interim analysis is any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to formal completion of a trial. Because the number, methods, and consequences of these comparisons affect the interpretation of the trial, all interim analyses should be carefully planned in advance and described in the protocol. Special circumstances may dictate the need for an interim analysis that was not defined at the start of a trial. In these cases, a protocol amendment describing the interim analysis should be completed prior to unblinded access to treatment comparison data. When an interim analysis is planned with the intention of deciding whether or not to terminate a trial, this is usually accomplished by the use of a group sequential design that employs statistical monitoring schemes as guidelines (see section 3.4). The goal of such an interim analysis is to stop the trial early if the superiority of the treatment under study is clearly established, if the demonstration of a relevant treatment difference has become unlikely, or if unacceptable adverse effects are apparent. Generally, boundaries for monitoring efficacy require more evidence to terminate a trial early (i.e., they are more conservative) than boundaries for monitoring safety. When the trial design and monitoring objective involve multiple endpoints, then this aspect of multiplicity may also need to be taken into account.

The protocol should describe the schedule of interim analyses or, at least, the considerations that will govern its generation, for example, if flexible alpha spending function approaches are to be employed. Further details may be given in a protocol amendment before the time of the first interim analysis. The stopping guidelines and their properties should be clearly described in the protocol or amendments. The potential effects of early stopping on the analysis of other important variables should also be considered. This material should be written or approved by the data monitoring committee (see section 4.6), when the trial has one. Deviations from the planned procedure always bear the potential of invalidating the trial results. If it becomes necessary to make changes to the trial, any consequent changes to the statistical procedures should be specified in an amendment to the protocol at the earliest opportunity, especially discussing the impact on any analysis and inferences that such changes may cause. The procedures selected should always ensure that the overall probability of Type I error is controlled.

The execution of an interim analysis should be a completely confidential process because unblinded data and results are potentially involved. All staff involved in the conduct of the trial should remain blind to the results of such analyses, because of the possibility that their attitudes to the trial will be modified and cause changes in the characteristics of patients to be recruited or biases in treatment comparisons. This principle may be applied to all investigator staff and to staff employed by the sponsor except for those who are directly involved in the execution of the interim analysis. Investigators should be informed only about the decision to continue or to discontinue the trial, or to implement modifications to trial procedures.

Most clinical trials intended to support the efficacy and safety of an investigational product should proceed to full completion of planned sample size accrual; trials should be stopped early only for ethical reasons or if the power is no longer acceptable. However, it is recognized that drug development plans involve the need for sponsor access to comparative treatment data for a variety of reasons, such as planning other trials. It is also recognized that only a subset of trials will involve the study of serious life-threatening outcomes or mortality which may need sequential monitoring of accruing comparative treatment effects for ethical reasons. In either of these situations, plans for interim statistical analysis should be in place in the protocol or in protocol amendments prior to the unblinded access to comparative treatment data in order to deal with the potential statistical and operational bias that may be introduced.

For many clinical trials of investigational products, especially those that have major public health significance, the responsibility for monitoring comparisons of efficacy and/or safety outcomes should be assigned to an external independent group, often called an independent data monitoring committee (IDMC), a data and safety monitoring board, or a data monitoring committee, whose responsibilities should be clearly described.

When a sponsor assumes the role of monitoring efficacy or safety comparisons and therefore has access to unblinded comparative information, particular care should be taken to protect the integrity of the trial and to manage and limit appropriately the sharing of information. The sponsor should ensure and document that the internal monitoring committee has complied with written standard operating procedures and that minutes of decisionmaking meetings, including records of interim results, are maintained.

Any interim analysis that is not planned appropriately (with or without the consequences of stopping the trial early) may flaw the results of a trial and possibly weaken confidence in the conclusions drawn. Therefore, such analyses should be avoided. If unplanned interim analysis is conducted, the clinical study report should explain why it was necessary and the degree to which blindness had to be broken, and provide an assessment of the potential magnitude of bias introduced and the impact on the interpretation of the results.

4.6 Role of Independent Data Monitoring Committee (IDMC)(see sections 1.25 and 5.5.2 of ICH E6)

An IDMC may be established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy variables and recommend to the sponsor whether to continue, modify or terminate a trial. The IDMC should have written operating procedures and maintain records of all its meetings, including interim results; these should be available for review when the trial is complete. The independence of the IDMC is intended to control the sharing of important comparative information and to protect the integrity of the clinical trial from adverse impact resulting from access to trial information. The IDMC is a separate entity from an institutional review board (IRB) or an independent ethics committee (IEC), and its composition should include clinical trial scientists knowledgeable in the appropriate disciplines, including statistics.

When there are sponsor representatives on the IDMC, their role should be clearly defined in the operating procedures of the committee (for example, covering whether or not they can vote on key issues). Since these sponsor staff would have access to unblinded information, the procedures should also address the control of dissemination of interim trial results within the sponsor organization.

V. Data Analysis Considerations

5.1 Prespecification of the Analysis

When designing a clinical trial, the principal features of the eventual statistical analysis of the data should be described in the statistical section of the protocol. This section should include all the principal features of the proposed confirmatory analysis of the primary variable(s) and the way in which anticipated analysis problems will be handled. In the case of exploratory trials, this section could describe more general principles and directions.

The statistical analysis plan (see Glossary) may be written as a separate document to be completed after finalizing the protocol. In this document, a more technical and detailed elaboration of the principal features stated in the protocol may be included (see section 7.1). The plan may include detailed procedures for executing the statistical analysis of the primary and secondary variables and other data. The plan should be reviewed and possibly updated as a result of the blind review of the data (see section 7.1 for definition) and should be finalized before breaking the blind. Formal records should be kept of when the statistical analysis plan was finalized as well as when the blind was subsequently broken.

If the blind review suggests changes to the principal features stated in the protocol, these should be documented in a protocol amendment. Otherwise, it should suffice to update the statistical analysis plan with the considerations suggested from the blind review. Only results from analyses envisaged in the protocol (including amendments) can be regarded as confirmatory.

In the statistical section of the clinical study report, the statistical methodology should be clearly described including when in the clinical trial process methodology decisions were made (see ICH E3).

5.2 Analysis Sets

The set of subjects whose data are to be included in the main analyses should be defined in the statistical section of the protocol. In addition, documentation for all subjects for whom trial procedures (e.g., run-in period) were initiated may be useful. The content of this subject documentation depends on detailed features of the particular trial, but at least demographic and baseline data on disease status should be collected whenever possible.

If all subjects randomized into a clinical trial satisfied all entry criteria, followed all trial procedures perfectly with no losses to followup, and provided complete data records, then the set of subjects to be included in the analysis would be self-evident. The design and conduct of a trial should aim to approach this ideal as closely as possible, but, in practice, it is doubtful if it can ever be fully achieved. Hence, the statistical section of the protocol should address anticipated problems prospectively in terms of how these affect the subjects and data to be analyzed. The protocol should also specify procedures aimed at minimizing any anticipated irregularities in study conduct that might impair a satisfactory analysis, including various types of protocol violations, withdrawals and missing values. The protocol should consider ways both to reduce the frequency of such problems and to handle the problems that do occur in the analysis of data. Possible amendments to the way in which the analysis will deal with protocol violations should be identified during the blind review. It is desirable to identify any important protocol violation with respect to the time when it occurred, its cause, and its influence on the trial result. The frequency and type of protocol violations, missing values, and other problems should be documented in the clinical study report and their potential influence on the trial results should be described (see ICH E3).

Decisions concerning the analysis set should be guided by the following principles: (1) To minimize bias and (2) to avoid inflation of Type I error.

5.2.1 Full Analysis Set

The intention-to-treat (see Glossary) principle implies that the primary analysis should include all randomized subjects. Compliance with this principle would necessitate complete followup of all randomized subjects for study outcomes. In practice, this ideal may be difficult to achieve, for reasons to be described. In this document, the term ''full analysis set'' is used to describe the analysis set which is as complete as possible and as close as possible to the intention-to-treat ideal of including all randomized subjects. Preservation of the initial randomization in analysis is important in preventing bias and in providing a secure foundation for statistical tests. In many clinical trials, the use of the full analysis set provides a conservative strategy. Under many circumstances, it may also provide estimates of treatment effects that are more likely to mirror those observed in subsequent practice.

There are a limited number of circumstances that might lead to excluding randomized subjects from the full analysis set, including the failure to satisfy major entry criteria (eligibility violations), the failure to take at least one dose of trial medication, and the lack of any data post randomization. Such exclusions should always be justified. Subjects who fail to satisfy an entry criterion may be excluded from the analysis without the possibility of introducing bias only under the following circumstances:

(i) The entry criterion was measured prior to randomization.

(ii) The detection of the relevant eligibility violations can be made completely objectively.

(iii) All subjects receive equal scrutiny for eligibility violations. (This may be difficult to ensure in an open-label study, or even in a double-blind study if the data are unblinded prior to this scrutiny, emphasizing the importance of the blind review.)

(iv) All detected violations of the particular entry criterion are excluded.

In some situations, it may be reasonable to eliminate from the set of all randomized subjects any subject who took no trial medication. The intention-to-treat principle would be preserved despite the exclusion of these patients provided, for example, that the decision of whether or not to begin treatment could not be influenced by knowledge of the assigned treatment. In other situations it may be necessary to eliminate from the set of all randomized subjects any subject without data post randomization. No analysis should be considered complete unless the potential biases arising from these specific exclusions, or any others, are addressed.

When the full analysis set of subjects is used, violations of the protocol that occur after randomization may have an impact on the data and conclusions, particularly if their occurrence is related to treatment assignment. In most respects, it is appropriate to include the data from such subjects in the analysis, consistent with the intention-to-treat principle. Special problems arise in connection with subjects withdrawn from treatment after receiving one or more doses who provide no data after this point, and subjects otherwise lost to followup, because failure to include these subjects in the full analysis set may seriously undermine the approach. Measurements of primary variables made at the time of the loss to follow-up of a subject for any reason, or subsequently collected in accordance with the intended schedule of assessments in the protocol, are valuable in this context; subsequent collection is especially important in studies where the primary variable is mortality or serious morbidity. The intention to collect data in this way should be described in the protocol. Imputation techniques, ranging from the carrying forward of the last observation to the use of complex mathematical models, may also be used in an attempt to compensate for missing data. Other methods employed to ensure the availability of measurements of primary variables for every subject in the full analysis set may require some assumptions about the subjects' outcomes or a simpler choice of outcome (e.g., success/failure). The use of any of these strategies should be described and justified in the statistical section of the protocol, and the assumptions underlying any mathematical models employed should be clearly explained. It is also important to demonstrate the robustness of the corresponding results of analysis, especially when the strategy in question could itself lead to biased estimates of treatment effects.

Because of the unpredictability of some problems, it may sometimes be preferable to defer detailed consideration of the manner of dealing with irregularities until the blind review of the data at the end of the trial, and, if so, this should be stated in the protocol.

5.2.2 Per Protocol Set

The ''per protocol'' set of subjects, sometimes described as the ''valid cases,'' the ''efficacy'' sample, or the ''evaluable subjects'' sample, defines a subset of the subjects in the full analysis set who are more compliant with the protocol and is characterized by criteria such as the following:

(i) The completion of a certain prespecified minimal exposure to the treatment regimen;

(ii) The availability of measurements of the primary variable(s);

(iii) The absence of any major protocol violations, including the violation of entry criteria.

The precise reasons for excluding subjects from the per protocol set should be fully defined and documented before breaking the blind in a manner appropriate to the circumstances of the specific trial.

The use of the per protocol set may maximize the opportunity for a new treatment to show additional efficacy in the analysis, and most closely reflects the scientific model underlying the protocol. However, the corresponding test of the hypothesis and estimate of the treatment effect may or may not be conservative, depending on the trial. The bias, which may be severe, arises from the fact that adherence to the study protocol may be related to treatment and outcome.

The problems that lead to the exclusion of subjects to create the per protocol set, and other protocol violations, should be fully identified and summarized. Relevant protocol violations may include errors in treatment assignment, the use of excluded medication, poor compliance, loss to followup, and missing data. It is good practice to assess the pattern of such problems among the treatment groups with respect to frequency and time to occurrence.

5.2.3 Roles of the Different Analysis Sets

In general, it is advantageous to demonstrate a lack of sensitivity of the principal trial results to alternative choices of the set of subjects analyzed. In confirmatory trials, it is usually appropriate to plan to conduct both an analysis of the full analysis set and a per protocol analysis, so that any differences between them can be the subject of explicit discussion and interpretation. In some cases, it may be desirable to plan further exploration of the sensitivity of conclusions to the choice of the set of subjects analyzed. When the full analysis set and the per protocol set lead to essentially the same conclusions, confidence in the trial results is increased, bearing in mind, however, that the need to exclude a substantial proportion of subjects from the per protocol analysis throws some doubt on the overall validity of the trial.

The full analysis set and the per protocol set play different roles in superiority trials (which seek to show the investigational product to be superior) and in equivalence or noninferiority trials (which seek to show the investigational product to be comparable, see section 3.3.2). In superiority trials, the full analysis set is used in the primary analysis (apart from exceptional circumstances) because it tends to avoid over-optimistic estimates of efficacy resulting from a per protocol analysis. This is because the noncompliers included in the full analysis set will generally diminish the estimated treatment effect. However, in an equivalence or noninferiority trial, use of the full analysis set is generally not conservative and its role should be considered very carefully.

5.3 Missing Values and Outliers

Missing values represent a potential source of bias in a clinical trial. Hence, every effort should be undertaken to fulfill all the requirements of the protocol concerning the collection and management of data. In reality, however, there will almost always be some missing data. A trial may be regarded as valid, nonetheless, provided the methods of dealing with missing values are sensible, particularly if those methods are predefined in the protocol. Definition of methods may be refined by updating this aspect in the statistical analysis plan during the blind review. Unfortunately, no universally applicable methods of handling missing values can be recommended. An investigation should be made concerning the sensitivity of the results of analysis to the method of handling missing values, especially if the number of missing values is substantial.

A similar approach should be adopted to exploring the influence of outliers, the statistical definition of which is, to some extent, arbitrary. Clear identification of a particular value as an outlier is most convincing when justified medically as well as statistically, and the medical context will then often define the appropriate action. Any outlier procedure set out in the protocol or the statistical analysis plan should be such as not to favor any treatment group a priori. Once again, this aspect of the analysis can be usefully updated during blind review. If no procedure for dealing with outliers was foreseen in the trial protocol, one analysis with the actual values and at least one other analysis eliminating or reducing the outlier effect should be performed and differences between their results discussed.

5.4 Data Transformation

The decision to transform key variables prior to analysis is best made during the design of the trial on the basis of similar data from earlier clinical trials. Transformations (e.g., square root, logarithm) should be specified in the protocol and a rationale provided, especially for the primary variable(s). The general principles guiding the use of transformations to ensure that the assumptions underlying the statistical methods are met are to be found in standard texts; conventions for particular variables have been developed in a number of specific clinical areas. The decision on whether and how to transform a variable should be influenced by the preference for a scale that facilitates clinical interpretation.

Similar considerations apply to other derived variables, such as the use of change from baseline, percentage change from baseline, the ''area under the curve'' of repeated measures, or the ratio of two different variables. Subsequent clinical interpretation should be carefully considered, and the derivation should be justified in the protocol. Closely related points are made in section 2.2.2.

5.5 Estimation, Confidence Intervals, and Hypothesis Testing

The statistical section of the protocol should specify the hypotheses that are to be tested and/or the treatment effects that are to be estimated in order to satisfy the primary objectives of the trial. The statistical methods to be used to accomplish these tasks should be described for the primary (and preferably the secondary) variables, and the underlying statistical model should be made clear. Estimates of treatment effects should be accompanied by confidence intervals, whenever possible, and the way in which these will be calculated should be identified. A description should be given of any intentions to use baseline data to improve precision or to adjust estimates for potential baseline differences, for example, by means of analysis of covariance.

It is important to clarify whether one- or two-sided tests of statistical significance will be used and, in particular, to justify prospectively the use of one-sided tests. If hypothesis tests are not considered appropriate, then the alternative process for arriving at statistical conclusions should be given. The issue of one-sided or two-sided approaches to inference is controversial, and a diversity of views can be found in the statistical literature. The approach of setting Type I errors for one-sided tests at half the conventional Type I error used in two-sided tests is preferable in regulatory settings. This promotes consistency with the two-sided confidence intervals that are generally appropriate for estimating the possible size of the difference between two treatments.

The particular statistical model chosen should reflect the current state of medical and statistical knowledge about the variables to be analyzed as well as the statistical design of the trial. All effects to be fitted in the analysis (for example, in analysis of variance models) should be fully specified, and the manner, if any, in which this set of effects might be modified in response to preliminary results should be explained. The same considerations apply to the set of covariates fitted in an analysis of covariance. (See also section 5.7.) In the choice of statistical methods, due attention should be paid to the statistical distribution of both primary and secondary variables. When making this choice (for example between parametric and nonparametric methods), it is important to bear in mind the need to provide statistical estimates of the size of treatment effects together with confidence intervals (in addition to significance tests).

The primary analysis of the primary variable should be clearly distinguished from supporting analyses of the primary or secondary variables. Within the statistical section of the protocol or the statistical analysis plan there should also be an outline of the way in which data other than the primary and secondary variables will be summarized and reported. This should include a reference to any approaches adopted for the purpose of achieving consistency of analysis across a range of trials, for example, for safety data.

Modeling approaches that incorporate information on known pharmacological parameters, the extent of protocol compliance for individual subjects, or other biologically based data may provide valuable insights into actual or potential efficacy, especially with regard to estimation of treatment effects. The assumptions underlying such models should always be clearly identified, and the limitations of any conclusions should be carefully described.

5.6 Adjustment of Significance and Confidence Levels

When multiplicity is present, the usual frequentist approach to the analysis of

clinical trial data may necessitate an adjustment to the Type I error. Multiplicity may arise, for example, from multiple primary variables (see section 2.2.2), multiple comparisons of treatments, repeated evaluation over time, and/or interim analyses (see section 4.5). Methods to avoid or reduce multiplicity are sometimes preferable when available, such as the identification of the key primary variable (multiple variables), the choice of a critical treatment contrast (multiple comparisons), and the use of a summary measure such as ''area under the curve'' (repeated measures). In confirmatory analyses, any aspects of multiplicity that remain after steps of this kind have been taken should be identified in the protocol; adjustment should always be considered and the details of any adjustment procedure or an explanation of why adjustment is not thought to be necessary should be set out in the analysis plan.

5.7 Subgroups, Interactions, and Covariates

The primary variable(s) is often systematically related to other influences apart from treatment. For example, there may be relationships to covariates such as age and sex, or there may be differences between specific subgroups of subjects, such as those treated at the different centers of a multicenter trial. In some instances, an adjustment for the influence of covariates or for subgroup effects is an integral part of the planned analysis and hence should be set out in the protocol. Pretrial deliberations should identify those covariates and factors expected to have an important influence on the primary variable(s), and should consider how to account for these in the analysis to improve precision and to compensate for any lack of balance between treatment groups. If one or more factors are used to stratify the design, it is appropriate to account for those factors in the analysis. When the potential value of an adjustment is in doubt, it is often advisable to nominate the unadjusted analysis as the one for primary attention, the adjusted analysis being supportive. Special attention should be paid to center effects and to the role of baseline measurements of the primary variable. It is not advisable to adjust the main analyses for covariates measured after randomization because they may be affected by the treatments.

The treatment effect itself may also vary with subgroup or covariate—for example, the effect may decrease with age or may be larger in a particular diagnostic category of subjects. In some cases such interactions are anticipated or are of particular prior interest (e.g., geriatrics); hence a subgroup analysis or a statistical model including interactions is part of the planned confirmatory analysis. In most cases, however, subgroup or interaction analyses are exploratory and should be clearly identified as such; they should explore the uniformity of any treatment effects found overall. In general, such analyses should proceed first through the addition of interaction terms to the statistical model in question, complemented by additional exploratory analysis within relevant subgroups of subjects, or within strata defined by the covariates. When exploratory, these analyses should be interpreted cautiously. Any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted.

5.8 Integrity of Data and Computer Software Validity

The credibility of the numerical results of the analysis depends on the quality and validity of the methods and software (both internally and externally written) used both for data management (data entry, storage, verification, correction, and retrieval) and for processing the data statistically. Data management activities should therefore be based on thorough and effective standard operating procedures. The computer software used for data management and statistical analysis should be reliable, and documentation of appropriate software testing procedures should be available.

VI. Evaluation of Safety and Tolerability

6.1 Scope of Evaluation

In all clinical trials, evaluation of safety and tolerability (see Glossary) constitutes an important element. In early phases this evaluation is mostly of an exploratory nature and is only sensitive to frank expressions of toxicity, whereas in later phases the establishment of the safety and tolerability profile of a drug can be characterized more fully in larger samples of subjects. Later phase controlled trials represent an important means of exploring, in an unbiased manner, any new potential adverse effects, even if such trials generally lack power in this respect.

Certain trials may be designed with the purpose of making specific claims about superiority or equivalence with regard to safety and tolerability compared to another drug or to another dose of the investigational drug. Such specific claims should be supported by relevant evidence from confirmatory trials, similar to that necessary for corresponding efficacy claims.

6.2 Choice of Variables and Data Collection

In any clinical trial, the methods and measurements chosen to evaluate the safety and tolerability of a drug will depend on a number of factors, including knowledge of the adverse effects of closely related drugs, information from nonclinical and earlier clinical trials and possible consequences of the pharmacodynamic/pharmacokinetic properties of the particular drug, the mode of administration, the type of subjects to be studied, and the duration of the trial. Laboratory tests concerning clinical chemistry and hematology, vital signs, and clinical adverse events (diseases, signs, and symptoms) usually form the main body of the safety and tolerability data. The occurrence of serious adverse events and treatment discontinuations due to adverse events are particularly important to register (see ICH E2A and ICH E3).

Furthermore, it is recommended that a consistent methodology be used for the data collection and evaluation throughout a clinical trial program to facilitate the combining of data from different trials. The use of a common adverse event dictionary is particularly important. This dictionary has a structure that makes it possible to summarize the adverse event data on three different levels: System-organ class, preferred term, or included term (see Glossary). The preferred term is the level on which adverse events usually are summarized, and preferred terms belonging to the same system-organ class could then be brought together in the descriptive presentation of data (see ICH M1).

6.3 Set of Subjects to be Evaluated and Presentation of Data

For the overall safety and tolerability assessment, the set of subjects to be summarized is usually defined as those subjects who received at least one dose of the investigational drug. Safety and tolerability variables should be collected as comprehensively as possible from these subjects, including type of adverse event, severity, onset, and duration (see ICH E2B). Additional safety and tolerability evaluations may be needed in specific subpopulations, such as females, the elderly (see ICH E7), the severely ill, or those who have a common concomitant treatment. These evaluations may need to address more specific issues (see ICH E3).

All safety and tolerability variables will need attention during evaluation, and the broad approach should be indicated in the protocol. All adverse events should be reported, whether or not they are considered to be related to treatment. All available data in the study population should be accounted for in the evaluation. Definitions of measurement units and reference ranges of laboratory variables should be made with care; if different units or different reference ranges appear in the same trial (e.g., if more than one laboratory is involved), then measurements should be appropriately standardized to allow a unified evaluation. Use of a toxicity grading scale should be prespecified and justified.

The incidence of a certain adverse event is usually expressed in the form of a proportion relating number of subjects experiencing events to number of subjects at risk. However, it is not always self-evident how to assess incidence. For example, depending on the situation, the number of exposed subjects or the extent of exposure (in person-years) could be considered for the denominator. Whether the purpose of the calculation is to estimate a risk or to make a comparison between treatment groups, it is important that the definition is given in the protocol. This is especially important if long-term treatment is planned and a substantial proportion of treatment withdrawals or deaths are expected. For such situations, survival analysis methods should be considered and cumulative adverse event rates calculated in order to avoid the risk of underestimation.

In situations when there is a substantial background noise of signs and symptoms (e.g., in psychiatric trials), one should consider ways for accounting for this in the estimation of risk for different adverse events. One such method is to make use of the ''treatment emergent'' (see Glossary) concept in which adverse events are recorded only if they emerge or worsen relative to pretreatment baseline.

Other methods to reduce the effect of the background noise may also be appropriate, such as ignoring adverse events of mild severity or requiring that an event should have been observed at repeated visits to qualify for inclusion in the numerator. Such methods should be explained and justified in the protocol.

6.4 Statistical Evaluation

The investigation of safety and tolerability is a multidimensional problem. Although some specific adverse effects can usually be anticipated and specifically monitored for any drug, the range of possible adverse effects is very large, and new and unforeseeable effects are always possible. Further, an adverse event experienced after a protocol violation, such as use of an excluded medication, may introduce a bias. This background underlies the statistical difficulties associated with the analytical evaluation of safety and tolerability of drugs, and means that conclusive information from confirmatory clinical trials is the exception rather than the rule.

In most trials, the safety and tolerability implications are best addressed by applying descriptive statistical methods to the data, supplemented by calculation of confidence intervals wherever this aids interpretation. It is also valuable to make use of graphical presentations in which patterns of adverse events are displayed both within treatment groups and within subjects.

The calculation of p-values is sometimes useful, either as an aid to evaluating a specific difference of interest or as a ''flagging'' device applied to a large number of safety and tolerability variables to highlight differences worthy of further attention. This is particularly useful for laboratory data, which otherwise can be difficult to summarize appropriately. It is recommended that laboratory data be subjected to both a quantitative analysis, e.g., evaluation of treatment means, and a qualitative analysis where counting of numbers above or below certain thresholds are calculated.

If hypothesis tests are used, statistical adjustments for multiplicity to quantify the Type I error are appropriate, but the Type II error is usually of more concern. Care should be taken when interpreting putative statistically significant findings when there is no multiplicity adjustment.

In the majority of trials, investigators are seeking to establish that there are no clinically unacceptable differences in safety and tolerability compared with either a comparator drug or a placebo. As is the case for noninferiority or equivalence evaluation of efficacy, the use of confidence intervals is preferred to hypothesis testing in this situation. In this way, the considerable imprecision often arising from low frequencies of occurrence is clearly demonstrated.

6.5 Integrated Summary

The safety and tolerability properties of a drug are commonly summarized across trials continuously during an investigational product's development and, in particular, at the time of a marketing application. The usefulness of this summary, however, is dependent on adequate and well-controlled individual trials with high data quality.

The overall usefulness of a drug is always a question of balance between risk and benefit. In a single trial, such a perspective could also be considered even if the assessment of risk/benefit usually is performed in the summary of the entire clinical trial program. (See section 7.2.2)

For more details on the reporting of safety and tolerability, see section 12 of ICH E3.

VII. Reporting

7.1 Evaluation and Reporting

As stated in the introduction, the structure and content of clinical study reports is the subject of ICH E3. That ICH guidance fully covers the reporting of statistical work, appropriately integrated with clinical and other material. The current section is therefore relatively brief.

During the planning phase of a trial, the principal features of the analysis should have been specified in the protocol as described in section 5. When the conduct of the trial is over and the data are assembled and available for preliminary inspection, it is valuable to carry out the blind review of the planned analysis also described in section 5. This pre-analysis review, blinded to treatment, should cover, for example, decisions concerning the exclusion of subjects or data from the analysis sets, the checking of possible transformations and definitions of outliers, the addition to the model of important covariates identified in other recent research, and the reconsideration of the use of parametric or nonparametric methods. Decisions made at this time should be described in the report and should be distinguished from those made after the statistician has had access to the treatment codes, as blind decisions will generally introduce less potential for bias. Statisticians or other staff involved in unblinded interim analysis should not participate in the blind review or in making modifications to the statistical analysis plan. When the blinding is compromised by the possibility that treatment-induced effects may be apparent in the data, special care will be needed for the blind review.

Many of the more detailed aspects of presentation and tabulation should be finalized at or about the time of the blind review so that, by the time of the actual analysis, full plans exist for all its aspects including subject selection, data selection and modification, data summary and tabulation, estimation, and hypothesis testing. Once data validation is complete, the analysis should proceed according to the predefined plans; the more these plans are adhered to, the greater the credibility of the results. Particular attention should be paid to any differences between the planned analysis and the actual analysis as described in the protocol, the protocol amendments, or the updated statistical analysis plan based on a blind review of data. A careful explanation should be provided for deviations from the planned analysis.

All subjects who entered the trial should be accounted for in the report, whether or not they are included in the analysis. All reasons for exclusion from analysis should be documented; for any subject included in the full analysis set but not in the per protocol set, the reasons for exclusion from the latter should also be documented. Similarly, for all subjects included in an analysis set, the measurements of all important variables should be accounted for at all relevant time-points.

The effect of all losses of subjects or data, withdrawals from treatment, and major protocol violations on the main analyses of the primary variable(s) should be considered carefully. Subjects lost to followup, withdrawn from treatment, or with a severe protocol violation should be identified and a descriptive analysis of them provided, including the reasons for their loss and its relationship to treatment and outcome.

Descriptive statistics form an indispensable part of reports. Suitable tables and/or graphical presentations should illustrate clearly the important features of the primary and secondary variables and of key prognostic and demographic variables. The results of the main analyses relating to the objectives of the trial should be the subject of particularly careful descriptive presentation. When reporting the results of significance tests, precise p-values (e.g., ''p=0.034'') should be reported rather than making exclusive reference to critical values.

Although the primary goal of the analysis of a clinical trial should be to answer the questions posed by its main objectives, new questions based on the observed data may well emerge during the unblinded analysis. Additional and perhaps complex statistical analysis may be the consequence. This additional work should be strictly distinguished in the report from work which was planned in the protocol.

The play of chance may lead to unforeseen imbalances between the treatment groups in terms of baseline measurements not predefined as covariates in the planned analysis but having some prognostic importance nevertheless. This is best dealt with by showing that an additional analysis which accounts for these imbalances reaches essentially the same conclusions as the planned analysis. If this is not the case, the effect of the imbalances on the conclusions should be discussed.

In general, sparing use should be made of unplanned analyses. Such analyses are often carried out when it is thought that the treatment effect may vary according to some other factor or factors. An attempt may then be made to identify subgroups of subjects for whom the effect is particularly beneficial. The potential dangers of over-interpretation of unplanned subgroup analyses are well known (see also section 5.7) and should be carefully avoided. Although similar problems of interpretation arise if a treatment appears to have no benefit or an adverse effect in a subgroup of subjects, such possibilities should be properly assessed and should therefore be reported.

Finally, statistical judgement should be brought to bear on the analysis, interpretation and presentation of the results of a clinical trial. To this end, the trial statistician should be a member of the team responsible for the clinical study report and should approve the clinical report.

7.2 Summarizing the Clinical Database

An overall summary and synthesis of the evidence on safety and efficacy from all the reported clinical trials is required for a marketing application (expert report in EU, integrated summary reports in the United States, gaiyou in Japan). This may be accompanied, when appropriate, by a statistical combination of results.

Within the summary a number of areas of specific statistical interest arise: Describing the demography and clinical features of the population treated during the course of the clinical trial program; addressing the key questions of efficacy by considering the results of the relevant (usually controlled) trials and highlighting the degree to which they reinforce or contradict each other; summarizing the safety information available from the combined database of all the trials whose results contribute to the marketing application; and identifying potential safety issues. During the design of a clinical program, careful attention should be paid to the uniform definition and collection of measurements which will facilitate subsequent interpretation of the series of trials, particularly if they are likely to be combined across trials. A common dictionary for recording the details of medication, medical history and adverse events should be selected and used. A common definition of the primary and secondary variables is nearly always worthwhile and is essential for meta-analysis. The manner of measuring key efficacy variables, the timing of assessments relative to randomization/entry, the handling of protocol violators and deviators, and perhaps the definition of prognostic factors should all be kept compatible unless there are valid reasons not to do so.

Any statistical procedures used to combine data across trials should be described in detail. Attention should be paid to the possibility of bias associated with the selection of trials, to the homogeneity of their results, and to the proper modeling of the various sources of variation. The sensitivity of conclusions to the assumptions and selections made should be explored.

7.2.1 Efficacy Data

Individual clinical trials should always be large enough to satisfy their objectives. Additional valuable information may also be gained by summarizing a series of clinical trials that address essentially identical key efficacy questions. The main results of such a set of trials should be presented in an identical form to permit comparison, usually in tables or graphs that focus on estimates plus confidence limits. The use of meta-analytic techniques to combine these estimates is often a useful addition because it allows a more precise overall estimate of the size of the treatment effects to be generated and provides a complete and concise summary of the results of the trials. Under exceptional circumstances, a meta-analytic approach may also be the most appropriate way, or the only way, of providing sufficient overall evidence of efficacy via an overall hypothesis test. When used for this purpose, the meta-analysis should have its own prospectively written protocol.

7.2.2 Safety Data

In summarizing safety data, it is important to examine the safety database thoroughly for any indications of potential toxicity and to follow up any indications by looking for an associated supportive pattern of observations. The combination of the safety data from all human exposure to the drug provides an important source of information because its larger sample size provides the best chance of detecting the rarer adverse events and, perhaps, of estimating their approximate incidence. However, incidence data from this database are difficult to evaluate because of the lack of a comparator group, and data from comparative trials are especially valuable in overcoming this difficulty. The results from trials which use a common comparator (placebo or specific active comparator) should be combined and presented separately for each comparator providing sufficient data.

All indications of potential toxicity arising from exploration of the data should be reported. The evaluation of the reality of these potential adverse effects should take into account the issue of multiplicity arising from the numerous comparisons made. The evaluation should also make appropriate use of survival analysis methods to exploit the potential relationship of the incidence of adverse events to duration of exposure and/or followup. The risks associated with identified adverse effects should be appropriately quantified to allow a proper assessment of the risk/benefit relationship.

Annex 1 Glossary

Bayesian approaches—Approaches to data analysis that provide a posterior probability distribution for some parameter (e.g., treatment effect), derived from the observed data and a prior probability distribution for the parameter. The posterior distribution is then used as the basis for statistical inference.

Bias (statistical and operational)—The systematic tendency of any factorsassociated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value. Bias introduced through deviations in conduct is referred to as ''operational'' bias. The other sources of bias listed above are referred to as ''statistical.''

Blind review—The checking and assessment of data during the period of time between trial completion (the last observation on the last subject) and the breaking of the blind, for the purpose of finalizing the planned analysis.

Content validity—The extent to which a variable (e.g., a rating scale) measures what it is supposed to measure.

Double dummy—A technique for retaining the blind when administering supplies in a clinical trial, when the two treatments cannot be made identical. Supplies are prepared for Treatment A (active and indistinguishable placebo) and for Treatment B (active and indistinguishable placebo). Subjects then take two sets of treatment; either A (active) and B (placebo), or A (placebo) and B (active).

Dropout—A subject in a clinical trial who for any reason fails to continue in the trial until the last visit required of him/her by the study protocol.

Equivalence trial—A trial with the primary objective of showing that the response to two or more treatments differs by an amount which is clinically unimportant. This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence margin of clinically acceptable differences.

Frequentist methods—Statistical methods, such as significance tests and confidence intervals, which can be interpreted in terms of the frequency of certain outcomes occurring in hypothetical repeated realizations of the same experimental situation.

Full analysis set—The set of subjects that is as close as possible to the ideal implied by the intention-to-treat principle. It is derived from the set of all randomized subjects by minimal and justified elimination of subjects.

Generalizability, generalization—The extent to which the findings of a clinical trial can be reliably extrapolated from the subjects who participated in the trial to a broader patient population and a broader range of clinical settings.

Global assessment variable—A single variable, usually a scale of ordered categorical ratings, that integrates objective variables and the investigator's overall impression about the state or change in state of a subject.

Independent data monitoring committee (IDMC) (data and safety monitoring board, monitoring committee, data monitoring committee)—An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Intention-to-treat principle—The principle that asserts that the effect of a treatment policy can be best assessed by evaluating on the basis of the intention to treat a subject (i.e., the planned treatment regimen) rather than the actual treatment given. It has the consequence that subjects allocated to a treatment group should be followed up, assessed, and analyzed as members of that group irrespective of their compliance with the planned course of treatment.

Interaction (qualitative and quantitative)—The situation in which a treatment contrast (e.g., difference between investigational product and control) is dependent on another factor (e.g., center). A quantitative interaction refers to the case where the magnitude of the contrast differs at the different levels of the factor, whereas for a qualitative interaction the direction of the contrast differs for at least one level of the factor.

Interrater reliability—The property of yielding equivalent results when used by different raters on different occasions.

Intrarater reliability—The property of yielding equivalent results when used by the same rater on different occasions.

Interim analysis—Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial.

Meta-analysis—The formal evaluation of the quantitative evidence from two or more

trials bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes also used to refer to the combination of the raw data.

Multicenter trial—A clinical trial conducted according to a single protocol but at more than one site and, therefore, carried out by more than one investigator.

Noninferiority trial—A trial with the primary objective of showing that the response to the investigational product is not clinically inferior to a comparative agent (active or placebo control).

Preferred and included terms—In a hierarchical medical dictionary, for example, the World Health Organization's Adverse Reaction Terminology (WHO-Art), the included term is the lowest level of dictionary term to which the investigator description is coded. The preferred term is the level of grouping of included terms typically used in reporting frequency of occurrence. For example, the investigator text ''Pain in the left arm'' might be coded to the included term ''Joint pain,'' which is reported at the preferred term level as ''Arthralgia.''

Per protocol set (valid cases, efficacy sample, evaluable subjects sample)—The set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model. Compliance covers such considerations as exposure to treatment, availability of measurements, and absence of major protocol violations.

Safety and tolerability—The safety of a medical product concerns the medical risk to the subject, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diseases, signs and symptoms), and other special safety tests (e.g., electrocardiograms, ophthalmology). The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the subject.

Statistical analysis plan—A statistical analysis plan is a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.

Superiority trial—A trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control).

Surrogate variable—A variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical.

Treatment effect—An effect attributed to a treatment in a clinical trial. In most clinical trials, the treatment effect of interest is a comparison (or contrast) of two or more treatments.

Treatment emergent—An event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state.

Trial statistician—A statistician who has a combination of education/training and experience sufficient to implement the principles in this guidance and who is responsible for the statistical aspects of the trial.

Dated: September 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24754 Filed 9–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9879–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First Quarter, 1998

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published during January, February, and March of 1998 that relate to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that may be potentially covered under Medicare.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

FOR FURTHER INFORMATION CONTACT: Bridget Wilhite, (410) 786–5248 (For Medicare instruction information);

Betty Stanton, (410) 786–3247 (For Medicaid instruction information);

Sharon Hippler, (410) 786–4633 (For Food and Drug Administration-approved investigational device exemption information);

Kristy Nishimoto, (410) 786–8517 (For all other information).

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 38 million Medicare beneficiaries and 36 million Medicaid recipients. Administration of these programs involves (1) providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public, and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted the Secretary under sections 1102, 1871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the **Federal Register** at least every 3 months a list of all Medicare manual instructions, interpretive rules, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame.

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, or Food and Drug Administration-approved investigational device exemptions published during the timeframe to determine whether any are of particular interest. We expect it to be used in concert with previously published notices. Most notably, those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) and the notice published March 31, 1993 (58 FR 16837), and those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989 publication (54 FR 34555).

To aid the reader, we have organized and divided this current listing into five addenda. Addendum I lists the publication dates of the most recent quarterly listings of program issuances.

Addendum II identifies previous **Federal Register** documents that contain a description of all previously

published HCFA Medicare and Medicaid manuals and memoranda.

Addendum III lists for each of our manuals or Program Memoranda, a HCFA transmittal number unique to that instruction and its subject matter. A transmittal may consist of a single instruction or many. Often it is necessary to use information in a transmittal in conjunction with information currently in the manuals.

Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the date published, the **Federal Register** citation, the parts of the Code of Federal Regulations (CFR) that have changed (if applicable), the agency file code number, the title of the regulation, the ending date of the comment period (if applicable), and the effective date (if applicable).

On September 19, 1995, we published a final rule (60 FR 48417) establishing in regulations at 42 CFR 405.201 *et seq.* that certain devices with an investigational device exemption approved by the Food and Drug Administration and certain services related to those devices may be covered under Medicare. It is HCFA's practice to announce in this quarterly notice all investigational device exemption categorizations, using the investigational device exemption numbers the Food and Drug Administration assigns. Addendum V includes listings of the Food and Drug Administration-approved investigational device exemption numbers that have been approved or revised during the quarter covered by this notice. The listings are organized according to the categories to which the device numbers are assigned (that is, Category A or Category B, and identified by the investigational device exemption number).

III. How To Obtain Listed Material

A. Manuals

An individual or organization interested in routinely receiving any manual and revisions to it may purchase a subscription to that manual. Those wishing to subscribe should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses:

Superintendent of Documents, Government Printing Office, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); or

National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, all manuals are available at the following Internet address: http://www.hcfa.gov/pubforms/progman.htm.

B. Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. Interested individuals may purchase individual copies or subscribe to the **Federal Register** by contacting the GPO at the address given above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is also available on 24x microfiche and as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

C. Rulings

We publish Rulings on an infrequent basis. Interested individuals can obtain copies from the nearest HCFA Regional Office or review them at the nearest regional depository library. We have, on occasion, published Rulings in the **Federal Register**. In addition, Rulings, beginning with those released in 1995, are available online, through the HCFA Home Page. The Internet address is http://www.hcfa.gov/regs/rulings.htm.

D. HCFA's Compact Disk-Read Only Memory (CD–ROM)

Our laws, regulations, and manuals are also available on CD–ROM, which may be purchased from GPO or NTIS on a subscription or single copy basis. The Superintendent of Documents list ID is HCLRM, and the stock number is 717–139–00000–3. The following material is on the CD–ROM disk:

- Titles XI, XVIII, and XIX of the Act.
- HCFA-related regulations.
- HCFA manuals and monthly revisions.
- HCFA program memoranda.

The titles of the Compilation of the Social Security Laws are current as of January 1, 1995. The remaining portions of CD–ROM are updated on a monthly basis.

Because of complaints about the unreadability of the Appendices (Interpretive Guidelines) in the State Operations Manual (SOM), as of March 1995, we deleted these appendices from CD–ROM. We intend to re-visit this issue in the near future, and, with the aid of newer technology, we may again be able to include the appendices on CD–ROM.

Any cost report forms incorporated in the manuals are included on the CD–ROM disk as LOTUS files. LOTUS software is needed to view the reports once the files have been copied to a personal computer disk.

IV. How To Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1400 designated libraries throughout the United States. Interested parties may examine the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as an FDL. To locate the nearest FDL, contact any library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of most Federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Superintendent of Documents numbers for each HCFA publication are shown in Addendum III, along with the HCFA publication and transmittal numbers. To help FDLs locate the instruction, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Home Health Agency Manual, (HCFA Pub. 11) transmittal entitled ''Treatment Codes for Home Health Services,'' use the

Superintendent of Documents No. HE 22.8/5 and the HCFA transmittal number 286.

V. General Information

It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. Copies can be purchased or reviewed as noted above.

Questions concerning Medicare items in Addendum III may be addressed to Bridget Wilhite, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, Telephone (410) 786–5248.

Questions concerning Medicaid items in Addendum III may be addressed to Betty Stanton, Center for Medicaid State Operations, Policy Coordination and Planning Group, Health Care Financing Administration, S2–26–13, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–3247.

Questions concerning Food and Drug Administration-approved investigational device exemptions may be addressed to Sharon Hippler, Office of Clinical Standards and Quality, Coverage Analysis Group, Health Care Financing Administration, C4–11–04, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–4633.

Questions concerning all other information may be addressed to Kristy Nishimoto, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5–13–07, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–8517.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: September 8, 1998.

Pamela J. Gentry,

Director Office of Communications and Operations Support.

Addendum I

This Addendum lists the publication dates of the most recent quarterly listings of program issuances.

May 12, 1997 (62 FR 25957)
November 3, 1997 (62 FR 59358)
November 21, 1997 (62 FR 62325)
June 4, 1998 (63 FR 30499)
August 11, 1998 (63 FR 42857)

Addendum II—Description of Manuals, Memoranda, and HCFA Rulings

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[January 1998 Through March 1998]

Trans. No.	Manual/Subject/Publication No.
	Intermediary Manual Part 3—Claims Process (HCFA Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1731	• Reporting Outpatient Surgery and Other Services. Use of Modifiers in Reporting Hospital Outpatient Services.
1732	• Medicare Secondary Payment Modules. Payment Calculation for Inpatient Bills. Payment Calculation for Outpatient Bills.
1733	• Definition of Medicare Secondary Payer/Common Working File Terms.
1734	• Medical Review of Home Health Services. Home Health Certification and Plan of Care Data Elements. Treatment Codes for Home Health Services. Plan of Care. Medical Review of Skilled Nursing and Home Health Aide Hours for Determining Part-Time or Intermittent. Treatment Codes for Professional Services Required. Acceptable V Codes.
1735	• Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines. Mammography Screening.
1736	• Eligibility Data Available Part A Eligibility Data Security Requirements.
	Carriers Manual Part 3—Claims Process (HCFA Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1584	• Medicare Participating Physicians/Suppliers Directory.
1585	• Application of Foot Care Exclusions to Physicians' Services.
1586	• Medicare Secondary Payment Modules. Payment Calculation for Physician/Supplier Claims.
1587	• Identifying a Screening Mammography Claim. Medicare Summary Notice and Explanation of Medicare Benefits Messages. Remittance Advice Messages.
1588	• Chiropractic Services.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1998 Through March 1998]

Trans. No.	Manual/Subject/Publication No.
1589	• Medicare Secondary Payer Claims Processing Under Common Working File.
1590	• The Carrier Advisory Committee.
1591	• Payment for Oral Anti-Emetic Drugs When Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen.
1592	• Requirements for Processing Electronic Media Claims.
1593	• Definition of a Claim. Splitting Claims for Processing.
1594	• Durable Medical Equipment, Prosthetic, and Orthotic Supplies. Safeguards in Making Monthly Payments. Evidence of Medical Necessity—Oxygen Claim.
1595	• Claims Review for Global Surgeries.
1596	• Positron Emission Tomography Scans. Conditions for Medicare Coverage of Positron Emission Tomography Scans for Noninvasive Imaging of the Perfusion of the Heart. Conditions of Coverage of Positron Emission Tomography Scans for Characterization of Solitary Pulmonary Nodules and Positron Emission Tomography Scans Using FDG to Initially Stage Lung Cancer. Billing requirements for Positron Emission Tomography Scans. HCFA Common Procedures Coding System and Modifiers for Positron Emission Tomography Scans. Claims Processing Instructions for Positron Emission Tomography Scan Claims.
	Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–97–22	• Claims Processing for the Restructured Hospice Benefit Periods and Billing Clarification for Place of Service.
A–98–1	• Processing Claims for the Home Health Part A and Part B Shift.
A–98–2	• Developing Medicare Ambulance Rates.
A–98–3	• Medicare Home Health Benefit—Section 4615 of the Balanced Budget Act of 1997—Clarification That No Home Health Benefits are Authorized Based Solely On Drawing Blood.
A–98–4	• Implementation of Surety Bond Requirement for Home Health Agencies.
A–98–5	• Billing Requirements for Claims with Dates of Service on or After April 1, 1998 for Oral Anti-Nausea Drugs as Full Therapeutic Replacements for Intravenous Dosage Forms As Part of a Cancer Chemotherapeutic Regimen.
A–98–6	• Screening Pap Smear and Pelvic Examinations—The Balanced Budget Act of 1997.
A–98–7	• Extension of Due Date for Filing Provider 2552-96 Cost Reports.
A–98–8	• Reporting Outpatient Rehabilitation Services and All Comprehensive Outpatient Rehabilitation Facility Services Using HCFA Common Procedure Coding System.
A–98–9	• Positron Emission Tomography Scans.
	Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–97–14	• Maintenance Process for the 1998 Medicare Physician Fee Schedule Database.
B–97–15	• Screening Pap Smear and Pelvic Examinations—The Balanced Budget Act of 1997.
B–97–16	• Changes to Correct Coding Edits, Version 4.1.
B–97–17	• Private Contracts Between Beneficiaries and Physicians/Practitioners.
B–98–1	• Evaluating the Medical Necessity for Laboratory Panel Current Procedural Terminology Codes.
B–98–2	• Payment for the Services of a Certified Registered Nurse Anesthetist and a Anesthesiologist in a Single Anesthesia Procedure.
B–98–3	• Resolution of Problems in the Initial National Provider Identifier Enumeration Effort from the Unique Physician Identification Number Registry.
B–98–4	• Instructions to Implement the New Medicare Summary Notice.
B–98–5	• Provider Material to be Published in Carrier Bulletins.
B–98–6	• Durable Medical Equipment Regional Carrier Instructions for Denying Claims and Recovering Overpayments for Prescription Drugs Billed and/or Paid to Suppliers Not Licensed to Dispense Prescriptions Drugs.
B–98–7	• Ongoing Maintenance Process for the 1998 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule.
B–98–8	• Changes to the 1998 Medicare Physician Fee Schedule Database.
B–98–9	• Millennium Changes for Forms HCFA–1491, 1490S, and 1490U.
B–98–10	• Corrections to Correct Coding Edits, Version 4.0.
B–98–11	• Provider Material to be Published in Carrier Bulletin.
	Program Memorandum Intermediaries/Carriers (HCFA Pub. 60AB) (Superintendent of Documents No. HE 22.8/6–5)
AB–97–25	• Implementation of the New Payment Limit for Drugs and Biologicals.
AB–97–26	• Coverage and Interim Billing Instructions of Oral Anti-Nausea Drugs as Full Therapeutic Replacements for Intravenous Dosage Forms as Part of a Cancer Chemotherapeutic Regimen.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1998 Through March 1998]

Trans. No.		Manual/Subject/Publication No.
AB–97–27	•	Implementing Instructions—Positron Emission Tomography Scans for Characterizing Solitary Pulmonary Nodules or Staging Lung Cancer Performed on or After January 1, 1998.
AB–98–1	•	Balanced Budget Act Requirement to Furnish Diagnostic Information.
AB–98–2	•	Suspension of National Coverage Policy on Electrostimulation for Wound Healing—(Clarification of Program Memorandum B–97–11).
AB–98–3	•	Temporary National HCFA Common Procedures Coding System Codes.
AB–98–4	•	Implementation of the Office of the Inspector's General Fraud Hot Line Number on Medicare Beneficiary Notices.
AB–98–5	•	Gap-Filling Fee Schedule Amounts for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Using Fee Schedule Amounts for Comparable Items.
AB–98–6	•	Identifying Employer in Other-than-Data Match Group Health Plan Medicare Secondary Payer Recovery Situations.
AB–98–7	•	Implementation of 1998 Clinical Diagnostic Laboratory Fee Schedule and Mapping for 1998 Laboratory Coding Changes.
AB–98–8	•	New Interest Rate Payable on Clean Claims Not Paid Timely.
AB–98–9	•	Revised Inherent Reasonableness Policy for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.
AB–98–10	•	Modification of Medicare Coverage of Erythropoietin.
		Program Memorandum Regional Office General (HCFA Pub. 51) (Superintendent of Documents No. HE 22.28/5:90–1)
98–1	•	Surety Bond Regulation.
98–2	•	Home Health Agency Surety Bond Requirements.
		Program Memorandum Insurance Commissioners/Insurance Issuers (HCFA Pub. 82) (Superintendent of Documents No. HE 22.8/6–5)
98–01	•	Agent Commissions and Application Processing Delays.
		State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)
286	•	Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities.
1	•	The State Operations Manual Has Been Combined With the Material From the Regional Office Manual, and Will Serve as a Basic Guide to Policies and Procedures for Certification Purposes.
		Medicare Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)
726	•	Reporting Outpatient Surgery and Other Services. Use of Modifiers in Reporting Hospital Outpatient Services.
727	•	Billing for Mammography Screening
		Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)
286	•	Home Health Certification and Plan of Care. Treatment Codes for Home Health Services. Plan of Care. Coverage Compliance Review. Documentation of Skilled Nursing and Home Health Aide Hours. Treatment Codes for Professional Services Required. Acceptable V Codes.
		Skilled Nursing Facility (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)
352	•	Billing for Mammography Screening.
		Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
29	•	Billing for Mammography Screening by Rural Health Clinics and Federally Qualified Health Centers.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1998 Through March 1998]

Trans. No.	Manual/Subject/Publication No.
	Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/14)
103	• Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer.
	Provider Reimbursement Manual Part I (HCFA Pub. 15–I) (Superintendent of Documents No. HE 22.8/4)
401	• Regional Medicare Swing-Bed Skilled Nursing Facility Rates.
402	• Acquisitions. Betterments and Improvements.
	Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AH) (Superintendent of Documents No. HE 22.8/4)
5	• Independent Renal Dialysis Facility Statistical Data.
	State Medicaid Manual Part III—Eligibility (HCFA Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)
69	• Medicaid Payment for Recipients Under Group Health Plans.
	Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
98–1	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—December 1997.
97–2	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—January 1998.
97–3	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—February 1998.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 63 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
01/02/98 ...	89–105	.....	HCFA–1904–NC	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After October 1, 1997.	03/03/98	10/01/97
01/05/98 ...	292–355	413, 440, 441, 489	HCFA–1152–FC	Medicare and Medicaid Programs; Surety Bond and Capitalization Requirements for Home Health Agencies.	03/06/98	01/01/98
01/07/98 ...	687–690	405	HCFA–1908–IFC	Medicare Program; Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services).	03/09/98	03/09/98
01/09/98 ...	1659–1728	411, 424, 435, 455	HCFA–1809–P	Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships.	03/10/98	01/09/98
01/09/98 ...	1646–1658	411	HCFA–1902–IFC	Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions.	03/10/98	01/09/98
01/09/98 ...	1379–1383	413	HCFA–1004–FC	Medicare Program; Limit on the Valuation of a Depreciable Asset Recognized as an Allowance for Depreciation and Interest on Capital Indebtedness After a Change of Ownership.	03/10/98	01/09/98

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER—Continued

Publication date	FR Vol. 63 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
01/20/98 ...	2920–2926	.....	HCFA–1014–NC	Medicare Program; Request for Public Comments on Implementation of the Medicare+Choice Program, and Notice of Timeframes for Submission of Applications for Contracts.	02/19/98	01/20/98
1/20/98	2926–2939	424	HCFA–1864–P	Medicare Program; Additional Supplier Standards.	03/23/98	01/20/98
01/26/98 ...	3752–3756	.....	HCFA–2005–NC	Medicare Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 1998.	03/27/98	01/01/98
01/30/98 ...	5106–5139	413	HCFA–1808–F	Medicare and Medicaid Programs; Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Language Pathology, and Occupational Therapy Services.	.....	04/01/98
01/30/98 ...	4595–4597	400, 405, 410, 411, 414	HCFA–1884–CN	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule, Other Part B Payment Policies, and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998; Correction.	.....	10/31/97
02/04/98 ...	5809–5811	.....	HCFA–2011–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: July, August, September, October, and November 1997.	.....	02/04/98
02/11/98 ...	6864–6869	412, 413	HCFA–1731–F	Medicare Program; Payment for Preadmission Services.	.....	03/13/98
02/13/98 ...	7359–7360	.....	HCFA–1037–N	Medicare Program; Meeting of the Negotiated Rulemaking Committee on the Provider-Sponsored Organization Solvency Standards.	.....	02/13/98
02/17/98 ...	7743	416, 482, 485, 489	HCFA–3745–N	Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval; Extension of Comment Period.	03/03/98 04/20/98	02/17/98
02/19/98 ...	8462–8465	.....	HCFA–1897–N	Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or After October 1, 1997.	.....	10/01/97
03/04/98 ...	10732–10733	.....	HCFA–1038–N	Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies.	.....	03/04/98
03/04/98 ...	10730–10731	441, 489	HCFA–1152–F	Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies.	.....	03/04/98
03/04/98 ...	10641–10642	.....	HCFA–1036–N	Medicare Program; March 16–17, 1998, Meeting of the Practicing Physicians Advisory Council.	.....	03/04/98
03/05/98 ...	10921–10927	.....	HCFA–1103–GN	Medicare Program; HCFA Market Research for Providers and Other Partners.	05/04/98	03/04/98
03/06/98 ...	11147–11159	400, 409, 410, 411, 412, 413, 424, 440, 485, 488, 489, 498.	BPD–878–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates; Corrections.	.....	10/01/97
03/10/98 ...	11687–11688	.....	HCFA–1013–NC	Medicare and Medicaid Programs; Announcement of Additional Application From Hospital Requesting Waiver for Organ Procurement Service Area.	05/11/98	03/10/98

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER—Continued

Publication date	FR Vol. 63 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
03/10/98 ...	11649	411, 424, 435, 455	HCFA–1809–N	Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Extension of Comment Period.	05/11/98	03/10/98
03/10/98 ...	11686–11687	.....	HCFA–2021–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: December 1997 and January 1998.	.....	03/10/98
03/18/98 ...	13260–13262	.....	HCFA–3000–N	Medicare Programs; Solicitation of Proposals for a Demonstration Project for the Use of Informatics, Telemedicine, and Education in the Treatment of Diabetes Mellitus in the Rural and Inner-City Medicare Populations.	04/17/98	03/10/98
03/20/98 ...	13590–13608	400, 421	HCFA–7020-P	Medicare Program; Medicare Integrity Program, Intermediary and Carrier Functions, and Conflict of Interest Requirements.	05/19/98	03/20/98
03/25/98 ...	14506–14526	401, 403, 405, 410, 411, 413, 447, 466, 473, 493.	HCFA–1719–P	Medicare Program; ''Without Fault'' and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability.	05/26/98	03/25/98
03/31/98 ...	15315	413	HCFA–1808–CN	Medicare and Medicaid Programs; Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Language Pathology, and Occupational Therapy Services; Revised Effective Date and Technical Correction.	.....	04/10/98
03/31/98 ...	15718–15738	413	HCFA–1905–FC	Medicare Program; Schedule of Per-Beneficiary Limitations on Home Health Agency Costs for Cost Reporting Periods Beginning on or After October 1, 1997.	06/01/98	10/01/98

Categorization of Food and Drug Administration-Approved Investigational Device Exemptions

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes. Also, under the new categorization process to assist HCFA, the Food and Drug Administration assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following information presents the device number, category (in this case, A), and criterion code.

G970106 A1
G970124 A1
G970252 A2
G970281 A2
G970311 A2
G980018 A2
G980020 A1
G980025 A2
G980040 A2

The following information presents the device number, category (in this case, B), and criterion code.

G970219 B1
G970230 B4
G970250 B1
G970264 B1
G970285 B2
G970286 B4
G970294 B4
G970302 B4
G970307 B2
G970308 B1
G970310 B2
G970316 B2
G970317 B2
G970321 B4
G970322 B2
G980001 B2
G980002 B4
G980003 B4
G980006 B3
G980007 B2
G980009 B3
G980010 B2
G980014 B4
G980015 B2
G980016 B4
G980019 B1
G980021 B1
G980023 B2
G980027 B3
G980028 B1
G980029 B4
G980030 B1
G980031 B3
G980034 B2
G980036 B4
G980037 B4
G980038 B4
G980039 B2
G980041 B1

[FR Doc. 98–24804 Filed 9–15–98; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Technical Assistance Workshops for Programs Administered by the Division of Disadvantaged Assistance, Bureau of Health Professions

AGENCY: Health Resources and Services Administration.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that technical assistance workshops will be held for new and renewal applicants for fiscal year (FY) 1999 competitive grant cycle for the Health Careers Opportunity Programs.

FOR FURTHER INFORMATION CONTACT: Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A–09, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–2100.

SUPPLEMENTARY INFORMATION: The Division of Disadvantaged Assistance will be conducting application preparation technical assistance workshops for new and renewal applicants for the FY 1999 competitive grant cycles for the Health Careers Opportunity Program.

The workshops are scheduled as follows:

Crystal City Marriott, Arlington, VA. (800) 288–9290 (Registration Cut off Date September 21, 1998)—October 13–14

Embassy Suites Hotel Atlanta Airport, Atlanta, GA. (401) 767–1988 (Registration Cut off Date October 5, 1998)—October 19–20

Hyatt Regency O'Hare, Chicago, IL. (800) 233–1234 (Registration Cut off Date September 25, 1998)—October 19–20

Hobby Airport Hilton, Houston, TX. (713) 645–3000 (Registration Cut off Date September 30, 1998)—October 22–23

Embassy Suites Airport, Los Angeles, CA. (310) 215–1000 (Registration Cut off Date September 25, 1998)—October 22–23

The program will commence at 8:30 a.m. each day. Attendees must make their own hotel reservations. When making reservations, please reference the ''Health Careers Opportunity

Program Technical Assistance Workshop.'' Expenses incurred by attendees will not be supported by the Federal Government.

Participation in the technical assistance meetings does not assure approval and funding of applications submitted for competitive review.

Dated: September 10, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–24797 Filed 9–15–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered Species Permit Applications

AGENCY: Fish and Wildlife Service, DOI.

ACTION: Notice of receipt of permit applications.

SUMMARY: The following applicants have applied for a scientific research permit to conduct certain activities with endangered species pursuant to section 10 (a)(1)(A) of the Endangered Species Act of 1973, as amended (16 USC 1531 *et seq.*).

Permit No. 844857

Applicant: R.B. Riggan and Associates, Lisa Seneca, San Diego, California.

The applicant requests a permit to take (harass by survey) the Delhi Sands flower-loving fly (*Rhaphiomides terminatus abdominalis*) in conjunction with surveys in Riverside and San Bernardino Counties, California, for the purpose of enhancing its survival.

Permit No. 780195–4

Applicant: R.B. Riggan and Associates, Royce B. Riggan, Jr., San Diego, California.

The applicant requests a amendment to his permit to take (harass by survey) the Delhi Sands flower-loving fly (*Rhaphiomides terminatus abdominalis*) in conjunction with surveys in Riverside and San Bernardino Counties, California, for the purpose of enhancing its survival.

Permit No. 002243–4

Applicant: Bighorn Institute, Palm Desert, California.

The applicant requests a permit to take (capture, collect biological samples, and harass by radio-collaring) the Peninsular bighorn sheep (*Ovis canadensis cremnobates*) in conjunction with life history, captive propagation and population augmentation, and ecological research in Riverside and San Diego Counties, California, for the purpose of enhancing its survival.

Permit No. 827494

Applicant: Rick Riefner, Tustin, California.

The applicant requests an amendment to his permit to take (collect) the Riverside fairy shrimp (*Streptocephalus wootoni*) in conjunction with the collection of vernal pool algae in Riverside County, California, for the purpose of enhancing its survival.

DATES: Written comments on these permit applications must be received on or before October 16, 1998.

ADDRESSES: Written data or comments should be submitted to the Chief, Division of Consultation and Conservation Planning, Ecological Services, Fish and Wildlife Service, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181; Fax: (503) 231–6243. Please refer to the respective permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 20 days of the date of publication of this notice to the address above; telephone: (503) 231–2063. Please refer to the respective permit number for each application when requesting copies of documents.

Dated: September 9, 1998.

Thomas J. Dwyer,

Acting Regional Director, Region 1, Portland, Oregon.

[FR Doc. 98–24782 Filed 9–15–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Consideration of Alternative Methods of Funding National Fish and Wildlife Conservation Projects Through the Federal Aid in Sport Fish Restoration and Federal Aid in Wildlife Restoration Programs

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The Service is inviting comments from the public on different methods of funding important fish and wildlife conservation projects through the Federal Aid in Wildlife Restoration and Federal Aid in Sport Fish Restoration programs to replace the existing procedures. Existing grants,

projects approved for funding in Fiscal Year 1998, and projects presently being considered for funding in Fiscal Year 1999 will not be affected by this notice.

DATES: Comments due November 16, 1998.

ADDRESSES: U.S. Fish and Wildlife Service, Division of Federal Aid, MS 140 ARLSQ, 4401 North Fairfax Drive, Arlington, Virginia, 22203.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Taylor, Division of Federal Aid, U.S. Fish and Wildlife Service; (703) 358–2156.

SUPPLEMENTARY INFORMATION:

What Are These Grants?

The Federal Aid in Wildlife Restoration and Federal Aid in Sport Fish Restoration Acts authorize the Service to use up to 8 percent of the receipts accruing to the Wildlife Restoration fund and up to 6 percent of the Sport Fish Restoration fund for administering the programs. The remaining funds are apportioned to State fish and wildlife agencies for fish and wildlife restoration and management projects. Some of the money deducted for administration has been used at the Service's discretion for grants to fund important national fish and wildlife projects within the scope of the Acts that provide collective benefits for a majority of the States. This year $2 million is available for fisheries projects and $2 million is available for wildlife projects.

Why Are You Considering Alternatives?

The Service believes the present program needs to be eliminated or improved because it is too time consuming and inefficient to administer given the size of the program compared to the larger and more important statutory State grant program. This State grant program provides over $425 million each year for fish and wildlife restoration and management projects and needs more attention to policy development and coordination. In addition, different expectations and competition among applicants detract from harmonious partnerships among the Service, the States, and National conservation organizations.

Who May Apply for These Grants?

States, local governments, and charitable and educational institutions are eligible to apply for grants. Federal agencies may not receive grants, but may receive funding by transfers of funds through cooperative agreements.

How Can I Apply for a Grant?

Annually, we publish a notice in the **Federal Register** announcing procedures for submitting project proposals, deadlines, and the amount of money available for Sport Fish and Wildlife Restoration projects. The last procedures were published on April 10, 1998. Copies of the procedures are available from the Service at the address shown on this notice.

How Were Administrative Grants Managed in the Past?

We have followed procedures outlined below:

a. The Grants-in-Aid Committee (GIAC) of the International Association of Fish and Wildlife Agencies (IAFWA) provided us with a list of focus areas. The IAFWA is a national nonprofit organization representing the State fish and wildlife agencies who are the statutory recipients of the programs. Focus areas are types of priority projects on which States want to use grant funds.

b. We publish the procedures for applying for grants, eligibility criteria, focus areas, and due dates in the **Federal Register** about April.

c. Applicants must send an application to us by the due date which is usually in May or June.

d. We review all project proposals to determine if they are eligible for funding. Proposals that do not meet the standards published in the announcement are judged ineligible. Proposals that do meet the criteria are sent to the State members of the GIAC for ranking. We send letters to each applicant informing them whether their proposal was found eligible or ineligible.

e. The State members of the GIAC rate each proposal as high, medium, low, or do not fund. Their rankings are sent to us for compilation by the end of August.

f. We convert the rankings to a numerical score 0 to 3, calculate the average score for each proposal, and list the proposals in descending order of their averages.

g. The International Association of Fish and Wildlife Agencies, based on recommendations of the GIAC, recommends to us the projects that best address State needs and that should be funded.

h. The Service Director reviews the recommendations of the IAFWA and makes a final decision on which grants to fund.

i. We negotiate final terms of the grant agreement and award the grant to the successful applicants.

What Alternatives to the Present Process Are You Considering?

Alternative 1. No Program

a. There will be no national administrative grants program.

b. Funds traditionally available for this purpose ($2 million each for Sport Fish Restoration and the Wildlife Restoration Programs for Fiscal Years 1999) will be apportioned to the States.

c. States may cooperate among themselves on a regional or national level to fund projects of common interest using funds apportioned to individual State.

Alternative 2. Enhanced Existing Program With Federal Register Notice

a. IAFWA technical committees will identify specific national fish and wildlife conservation needs with all committee members having voting privileges.

b. National conservation needs developed by the IAFWA technical committees will be reviewed and prioritized by the GIAC and recommended to the IAFWA business meeting for approval.

c. The approved list of needs will then be forwarded to the Service Division of Federal Aid that will publish a **Federal Register** notice soliciting proposals to address specific national fish and wildlife conservation needs.

d. Proposals received by the Service will be forwarded to the IAFWA that will distribute them to the appropriate technical committees (again, all committee members having voting privileges) for review of eligibility and the selection of projects to be forwarded to the GIAC for ranking.

e. State members of the GIAC will rank all proposals, select those recommended for fundng, and forward their recommendations to the IAFWA business meeting for approval.

f. Proposals approved by the IAFWA will be submitted to the Service Director for final approval.

g. The Service Division of Federal Aid, will award and administer grants and cooperative agreements for approved projects.

Alternative 3. Enhance Existing Program Without Federal Notice

a. IAFWA technical committees will identify specific national fish and wildlife conservation needs with all Committee members having voting privileges. We will advance funds to the IAFWA to cover costs of administration for this and other steps of the process.

b. National fish and wildlife conservation needs developed by the IAFWA technical committees will be reviewed and prioritized by GIAC and recommended to the IAFWA business meeting for approval.

c. The IAFWA will then directly solicit proposals addressing the

approved list of needs. Proposals received will be forwarded by the IAFWA to the appropriate technical committees (again, all committee members having voting privileges) for review of eligibility and the selection of projects to be returned to the GIAC for ranking.

d. State members of the GIAC will rank all proposals, select those recommended for funding, and forward their recommendations to the IAFWA business meeting for approval.

e. Proposals approved by the IAFWA will be submitted to the Service Director for final approval.

f. The Service Division of Federal Aid, will award and administer grants and cooperative agreements for approved projects.

Alternative 4. Comprehensive Project Grant

a. IAFWA technical committees will identify specific national fish and wildlife conservation needs with all committee members having voting privileges.

b. National conservation needs developed by the IAFWA technical committees will be reviewed and prioritized by the GIAC and recommended to the IAFWA business meeting for approval.

c. The IAFWA will then directly solicit proposals addressing the approved list of needs.

d. Proposals received will be forwarded by the IAFWA to the appropriate IAFWA technical committees (again, all committee members having voting privileges) for review of eligibility and the selection of projects to be returned to the GIAC for ranking.

e. State members of the GIAC will rank all proposals, select those recommended for funding, and forward their recommendations to the IAFWA business meeting for approval.

f. The IAFWA will submit to the Service a single annual grant proposal that identifies the approved specific projects to be funded for both the Sport Fish Restoration and the Wildlife Restoration Programs.

g. Upon Service approval of the grant proposals, the IAFWA will administer funding for approved projects. The Service will advance funds to the GIAC to implement the grant proposal and cover costs of administration.

h. IAFWA will submit to the Service performance reports and financial status reports detailing expenditures associated with the individual projects funded by the comprehensive grants.

Alternative 5. Comprehensive Grant To Fund National Fish and Wildlife Needs

a. IAFWA technical committees will identify specific national fish and wildlife conservation needs with all committee members having voting privileges.

b. National fish and wildlife conservation needs developed by the IAFWA technical committees will be reviewed and prioritized by the GIAC and recommended to the IAFWA business meeting for approval.

c. The IAFWA will submit to the Service a single annual grant proposal that lists specific national fish and wildlife conservation needs for both the Sport Fish Restoration and Wildlife Restoration Programs.

d. Upon Service approval of the grant proposal, the IAFWA will directly solicit proposals to address the national fish and wildlife conservation needs identified in the grant.

e. Funds will be advanced to the IAFWA to implement the grant proposal and cover costs of administration.

f. IAFWA will submit to the Service performance reports and financial status reports detailing expenditures associated with the comprehensive grant.

Will You Consider Other Alternatives and Ideas?

Yes, we are interested in any thoughts or suggestions you have on improving the existing process.

Dated: September 10, 1998.

Jamie Rappaport Clark,

Director.

[FR Doc. 98–24803 Filed 9–15–98; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–962–1410–00–P]

Notice for Publication, AA–9238, AA–9244, AA–9247, AA–9250, and AA–10422; Alaska Native Claims Selection

In accordance with Departmental regulations 43 CFR 2650.7(d), notice is hereby given that decisions to issue conveyance under the provisions of Sec. 14(h)(1) of the Alaska Native Claims Settlement Act of December 18, 1971, (ANCSA), 43 U.S.C. 1601, 1613(h)(1), will be issued to the Calista Corporation for five sites aggregating approximately 56 acres. The lands involved are in the vicinity of Nunivak Island, Alaska, as follows:

Seward Meridian, Alaska

T. 1 N., R. 99 W.
T. 3 S., R. 95 W.
T. 1 S., R. 95 W.
T. 1 S., R. 100 W.
T. 2 S., R. 95 W.

A notice of the decisions will be published once a week, for four (4) consecutive weeks, in the *Anchorage Daily News.* Copies of the decisions may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599 ((907) 271–5960).

Any party claiming a property interest which is adversely affected by the decisions, shall have until October 16, 1998 to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management at the address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements in 43 CFR part 4, Subpart E, shall be deemed to have waived their rights.

Sherri D. Belenski,

Land Law Examiner, ANCSA Team, Branch of 962 Adjudication.

[FR Doc. 98–24795 Filed 9–15–98; 8:45 am]

BILLING CODE 4310–JA–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–411]

Certain Organic Photoconductor Drums and Products Containing Same; Notice of Commission Determination Not To Review Two Initial Determinations Terminating the Investigation as to Four Respondents on the Basis That Complainant Has Withdrawn Its Allegations of Infringement Against Those Respondents

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (ALJ's) initial determinations (IDs) (Orders Nos. 6 and 7) in the above-captioned investigation terminating the investigation as to four respondents on the basis of a withdrawal of the allegations made in the complaint against the subject respondents.

FOR FURTHER INFORMATION CONTACT: Jean Jackson, Esq., Office of the General Counsel, U.S. International Trade

Commission, telephone 202–205–3104. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 4, 1998, based on a complaint filed by Mitsubishi Chemical Corporation of Japan and Mitsubishi Chemical America, Inc., of White Plains New York (collectively, Mitsubishi). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain organic photoconductor drums and products containing same, by reason of infringement of two U.S. patents held by Mitsubishi.

On July 14, 1998, Mitsubishi and respondent Sinonar Corporation filed a joint motion under Commission rule 210.21(a) to terminate the investigation as to Sinonar based on Mitsubishi's withdrawal of the allegations in its complaint as to Sinonar. Upon examining documents and information provided by Sinonar, Mitsubishi concluded that Sinonar did not infringe its patents. On July 20, 1998, Mitsubishi and respondents Fuji Denki, Fuji Electric Co., Ltd, and U.S. Fuji Electric Inc. (collectively, Fuji) filed a similar joint motion to terminate the investigation as to the Fuji respondents. Upon examining documents and information provided by Fuji, Mitsubishi concluded that Fuji did not infringe the asserted patents. The Commission investigative attorney did not oppose either motion.

On August 21, 1998, The ALJ issued an ID (Order No. 6) granting the joint motion to terminate the investigation as to Sinonar. On the same date, he issued an ID (Order No. 7) terminating the investigation as to Fuji. No petitions for review were filed.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, and Commission rule 210.42, 19 CFR § 210.42.

Copies of the public version of the ALJ's ID, and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202–205–2000.

By order of the Commission.

Issued: September 10, 1998.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–24821 Filed 9–15–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–408]

Certain Recombinantly Produced Hepatitis B Vaccines and Products Containing Same; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation on the Basis of a Settlement Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (ALJ's) initial determination (ID) (Order No. 7) in the above-captioned investigation terminating the investigation on the basis of a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Jean Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–205–3104. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: This patent-based section 337 investigation was instituted by the Commission on May 11, 1998, on behalf of complainant Chiron Corporation (Chiron) of Emeryville, California. 63 FR 25869. The complaint alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain recombinantly produced hepatitis B vaccines that allegedly are covered by claims 4, 5, 7, or 8 of U.S. Letters Patent Re 35,749. The notice of investigation named SmithKline Beecham Biologicals, S.A. of Belgium and SmithKline Beecham Corporation of Philadelphia, Pennsylvania (collectively, ''SKB'') as respondents.

On August 7, 1998, complainant and respondents to the investigation filed a joint motion to terminate the investigation as to all issues based upon a settlement agreement, which was supported by the Commission investigative attorney. On August 18, 1998, the presiding ALJ granted the joint motion and issued an ID (Order No. 7) terminating the investigation on the basis of the settlement agreement. The ALJ found no indication that termination of the investigation would have an adverse impact on the public interest and that termination based on settlement is generally in the public interest. No petitions for review were filed.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and Commission rule 210.42, 19 CFR 210.42.

Copies of the public version of the ALJ's ID, and all other nonconfidential documents filed in connection with this investigation, are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202–205–2000.

By order of the Commission.

Issued: September 10, 1998.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–24822 Filed 9–15–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–373 (Final) and 731–TA–769–775 (Final)]

Stainless Steel Wire Rod [1] From Germany, Italy, Japan, Korea, Spain, Sweden, and Taiwan

Determinations

On the basis of the record [2] developed in the subject investigations, the United States International Trade Commission determines,[3] pursuant to section 705(b) of the Tariff Act of 1930 (the Act) (19 U.S.C. 1671d(b)), that an industry in the United States is materially injured by reason of imports from Italy of stainless steel wire rod, provided for in subheading 7221.00.00 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be subsidized by the Government of Italy and the European Union.

Also, the Commission determines,[4] pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)), that an industry in the United States is materially injured by reason of imports from Italy, Japan, Korea, Spain, Sweden, and Taiwan of stainless steel wire rod that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

Further, the Commission determines, pursuant to sections 735(b) and 771(24) of the Act (19 U.S.C. 1673d(b) and 1677(24)), that an industry in the United States is not threatened with material injury by reason of imports from Germany of stainless steel wire rod that have been found by the Department of Commerce to be sold in the United States at LTFV.[5 6 7 8]

Background

The Commission instituted these investigations effective July 30, 1997, following receipt of a petition filed with the Commission and the Department of Commerce by counsel on behalf of AL Tech Specialty Steel Corp., Dunkirk, NY; Carpenter Technology Corp., Reading, PA; Republic Engineered Steels, Inc., Massillon, OH; Talley Metals Technology, Inc., Hartsville, SC; and the United Steelworkers of America, AFL–CIO/CLC. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by the Department of Commerce that imports of stainless steel wire rod from Italy were being subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and imports of stainless steel wire rod from Germany, Italy, Japan, Korea, Spain, Sweden, and Taiwan were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of March 23, 1998 (63 FR 13872). The hearing was held in Washington, DC, on July 22, 1998, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on September 8, 1998. The views of the Commission are contained in USITC Publication 3126 (September 1998), entitled Stainless Steel Wire Rod From Germany, Italy, Japan, Korea, Spain, Sweden, and Taiwan: Investigations Nos. 701–TA–373 (Final) and 731–TA–769–775 (Final).

By order of the Commission.

Issued: September 10, 1998.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–24823 Filed 9–15–98; 8:45 am]

BILLING CODE 7020–02–P

[1] For purposes of these investigations, stainless steel wire rod is defined as stainless steel products that are hot-rolled or hot-rolled annealed and/or descaled rounds, squares, octagons, hexagons, or other shapes, in coils, that may also be coated with a lubricant containing copper, lime or oxalate. Stainless steel wire rod is made of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. Stainless steel wire rod is manufactured only by hot-rolling or hot-rolling, annealing, and/or pickling and/or descaling, is normally sold in coiled form, and is of solid cross section. Most stainless steel wire rod sold in the United States is round in cross-sectional shape, annealed and pickled, and later cold-finished into stainless steel wire or small-diameter bar. The most common size for stainless steel wire rod is 5.5 millimeters (0.217 inch) in diameter, which represents the smallest size that normally is produced on a rolling mill and is the size that most wire-drawing machines are set up to draw. The range of stainless steel wire rod sizes normally sold in the United States is between 0.20 inch and 1.312 inches in diameter. Stainless steel wire rod grades SF20T and K–M35FL are excluded from the scope of these investigations; additionally, grades Kanthal A–1, Kanthal AF, Kanthal A, Kanthal D, Kanthal DT, Alkrothal 14, Alkrothal 720, and Nikrothal 40 are excluded from the investigation concerning Sweden. Stainless steel wire rod is provided for in subheading 7221.00.00 of the Harmonized Tariff Schedule (HTS) with a 1998 column 1-general tariff rate of 2.8 percent *ad valorem*, applicable to products of ech of the subject countries.

[2] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

[3] Commissioners Carol T. Crawford and Thelma J. Askey dissenting and Commissioner Jennifer A. Hillman not participating.

[4] Commissioners CArol T. Crawford and Thelma J. Askey dissenting and Commissioner Jennifer A. Hillman not participating.

[5] Pursuant to 19 U.S.C. § 1677(24)(A)(i) and (iv), the Commission also finds that subject imports from Germany account for less than 3 percent of the volume of all such merchandise imported into the United States in the most recent 12-month period preceding the filing of the petition, but (Commissioner Carol T. Crawford dissenting) that there is a potential that such imports from Germany will imminetly account for mroe than 3 percent of total import volume of all such merchandise.

[6] Commissioner Carol T. Crawford finds subject imports from Germany to be negligible.

[7] Chairman Lynn M. Bragg finds a threat of material injury by reason of subject German imports.

[8] Commissioner Jennifer A. Hillman not participating.

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 98–43; Exemption Application No. D–10547, et al.]

Grant of Individual Exemptions; Individual Retirement Accounts (the IRAs) for Marcia A. Hendrichsen, Larry L. Hendrichsen, Lawrence D. Hendrichsen, Located in Burlington, IA; William H. Napier, George Rashid, Jr., Jake E. Rashid, Carl A. Saunders, and John C. Schuldt, Located in Fort Madison, IA (Collectively, the Participants), et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, D.C. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The

applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Individual Retirement Accounts (the IRAs) for Marcia A. Hendrichsen, Larry L. Hendrichsen, Lawrence D. Hendrichsen, Located in Burlington, Iowa; William H. Napier, George Rashid, Jr., Jake E. Rashid, Carl A. Saunders, and John C. Schuldt, Located in Fort Madison, Iowa (Collectively, the Participants)

[Prohibited Transaction Exemption 98–43; Exemption Application Number: D–10547]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the cash sale (the Sale) of certain membership units (the Units) in the Catfish Bend Casinos, L.C., by the IRAs [1] to the Participants, disqualified persons with respect to the IRAs, provided that the following conditions are met:

(a) The Sale of the Units by each IRA is a one-time transaction for cash;

(b) The terms and conditions of each Sale are at least as favorable to each IRA as those obtainable in an arm's length transaction with an unrelated party;

(c) Each IRA receives the fair market value of the Units at the time of each Sale; and

(d) Each IRA is not required to pay any commissions, costs or other expenses in connection with each Sale.

For a more complete statement of the facts and circumstances supporting the Department's decision to grant this exemption, refer to the notice of the proposed exemption published on Thursday, August 6, 1998 at 63 FR 42076.

For Further Information Contact: Mr. James Scott Frazier of the Department, telephone (202) 219–8881. (This is not a toll-free number).

R & J Hoffmann, Inc. Profit Sharing Plan (the Plan) Located in Fremont, California

[Prohibited Transaction Exemption 98–44; Exemption Application No. D–10572]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to: (1) the loan (the Loan) of $53,240 by the Plan to R & J Hoffmann, Inc. (the Employer), a disqualified person with respect to the Plan; and (2) the personal guarantee of the Loan by Richard and Angela Hoffmann (the Hoffmanns), provided the following conditions are satisfied: (a) the terms of the Loan are at least as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party; (b) the Loan does not exceed 25% of the assets of the Plan; (c) the Loan is secured by a second mortgage on certain real property (the Property) which has been appraised by a qualified independent appraiser to have a fair market value not less than 150% of the amount of the Loan plus the balance of the first mortgage which it secures; (d) the Hoffmanns have also personally guaranteed the Loan; (e) in the event that the fair market value of the Property is no longer adequate to secure all outstanding loans, additional property will be pledged to the Plan to secure the Loan at an amount equal to at least 150% of the outstanding principal balance of all loans secured by the Property; and (f) the Hoffmanns are the only Plan participants to be affected by the Loan.[2]

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 20, 1998 at 63 FR 38859.

For Further Information Contact: Gary H. Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Kilpatrick Investment Company Employee's Pension Plan (the Plan); Located in Oklahoma City, Oklahoma

[Prohibited Transaction Exemption 98–45; Application No.: D–10607]

Exemption

The restrictions of sections 406(a) and 406(b)(1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of 4975(c)(1)(A) through (E) of the Code, shall not apply to the past sale (the Sale) of improved real property (the Property) by the Plan to the Kilpatrick Investment Company (the Company), a party in interest with respect to the Plan provided the following conditions were met at the time of the Sale: (1) the terms of the Sale were at least as favorable as those the Plan could have obtained in an arm's length transaction with an unrelated party; (2) the fair market value of the Property was determined by an independent and qualified real estate appraiser; (3) the Sale price was equal to the greater of: (a) the fair market value of the Property at the time of the Sale, or (b) $134,600 (which represents the price the Plan originally paid for the Property plus the holding costs incurred by the Plan during the Plan's ownership of the Property); and (4) the Plan paid no commissions or expenses associated with the Sale.

Effective Date: If granted, this proposed exemption will be effective as of April 15, 1998.

For a more complete statement of facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption, refer to the notice of proposed exemption published on July 8, 1998 at 63 FR 36957.

For Further Information Contact: Allison Padams Lavigne of the Department, telephone (202) 219–8971. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemptions

[1] Because each IRA has only one participant, there is no jurisdiction under 29 CFR § 2510.3–3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

[2] Since the Hoffmanns are the sole owner of the Employer and the only participants in the Plan, there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3–3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 10th day of September, 1998.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, Department of Labor.

[FR Doc. 98–24800 Filed 9–15–98; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–10379, et al.]

Proposed Exemptions; John Taylor Fertilizers Company Profit Sharing Plan (the Plan)

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

Unless otherwise stated in the Notice of Proposed Exemption, all interested persons are invited to submit written comments, and with respect to exemptions involving the fiduciary prohibitions of section 406(b) of the Act, requests for hearing within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5507, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

John Taylor Fertilizers Company Profit Sharing Plan (The Plan) Sacramento, California

[Application No. D–10379]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975 (c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the Plan of an undivided 16.28% interest (Leasehold Interest) in a certain leasehold (Leasehold) of a professional office complex (Office Complex) located in Sacramento, California, to John Taylor Fertilizers Company (the Company), a party in interest with respect to the Plan, provided that the following conditions are satisfied:

(A) All terms of the transaction are at least as favorable to the Plan as those which the Plan could obtain in an arm's-length transaction with an unrelated party;

(B) The sale is a one-time transaction for cash;

(C) The Plan pays no commissions or other expenses relating to the sale;

(D) The purchase price is the greater of: (1) the fair market value of the Leasehold Interest as determined by a qualified, independent appraiser, or (2) the original acquisition cost, plus all costs attributable to holding the Leasehold Interest through the date of the sale;

(E) The Plan receives rental income due and owing to the Plan through the date of the sale.

Summary of Facts and Representations

1. The Plan is a profit sharing plan with 187 participants and total assets of $12,997,980 as of October 31, 1995. The Plan is sponsored by John Taylor Fertilizers Company, a California Corporation, with its principal offices in Sacramento, California, which is engaged in the business of manufacturing and selling fertilizers. Mr. John Taylor is the trustee of the Plan. It is represented that Mr. Taylor makes investment decisions for the Plan.

2. The Leasehold Interest which is owned by the Plan represents an undivided 16.28% interest in the Leasehold. The other owners of the remaining 83.72% of the Leasehold are: Amelia Richter, Mary Richter, and Richter Brothers, Inc., Profit Sharing Plan and Trust (Collectively, the Co-Owners). The underlying land on which the Office Complex is located is owned by Constance N. Elkus. It is represented that neither the Co-Owners nor Constance N. Elkus is related to the John Taylor Fertilizers Company.

3. The Leasehold consists of the Office Complex which is comprised of two one-story buildings, with a garden style layout, located at the northeast corner of Northrop Avenue and Fulton Avenue, in Sacramento, California. The combined floor area of the Office Complex which comprises the Leasehold is approximately 85,378 square feet. The Office Complex is located on a rectangular parcel, with 344 feet of frontage on Northrop Avenue and 249 feet on Fulton Avenue and is zoned for Business and Professional Use. The Leasehold has a remaining primary term of approximately 16 years with an option to renew for two periods of ten years each.

4. The Plan acquired its Leasehold Interest as a result of a successful judicial foreclosure action brought by the Plan and the Co-Owners in 1991, as follows. In 1984, the Plan invested $141,000 in a loan to a partnership, which was secured by a second deed of trust in the Leasehold. In 1987, the partnership defaulted on the Loan and the Plan, along with the Co-Owners, foreclosed on the Leasehold. Pursuant to the judicial foreclosure, which was approved by the Superior Court of California, Sacramento County, the Plan acquired its Leasehold Interest.

Subsequent to acquiring the ownership of the Leasehold Interest, the Plan, along with the Co-Owners of the Leasehold, paid off the first deed of trust. In this regard, the Plan paid an additional $195,603 to Aetna, the holder of the first deed of trust. In addition, after acquiring the Leasehold Interest, the Plan paid expenses, net of income, relating to the holding of the Leasehold Interest totaling $153,747. These Plan expenses of $153,747, plus the payments in satisfaction of the first deed of trust of $195,603, plus the original Loan amount of $141,000, equals the Plan's original acquisition plus holding costs of the Leasehold Interest. Accordingly, the Plan's total investment in the Leasehold Interest is $490,350.[1]

5. After the Plan acquired the Leasehold Interest, the space in the Office Complex was rented to various business and professional tenants. Accordingly, the Plan received rental income of approximately $91,000 between January 1, 1984 and August 3, 1990. Between August 30, 1990 and November 1992, the Plan's expenses equaled the Plan's rental income from the Leasehold Interest. However, since November of 1992, the Plan's expenses related to holding the Leasehold Interest exceeded the rental income by $1,490 per month.

6. As of August 2, 1996, the Office Complex had a 44.2% vacancy rate. It is represented that the Plan continues to lose money on the Leasehold Interest because of the high vacancy rate and the continuing expenses related to the Plan's holding of the Leasehold Interest. Accordingly, it is represented that the Plan's continued ownership of the Leasehold Interest is not in the best interests of Plan participants and beneficiaries.

In addition, it is represented that fair market value of the Leasehold Interest has declined in value during recent years, and for this reason, the Company proposes to purchase the Leasehold from the Plan and is requesting an exemption for its sale under the terms and conditions described herein.

7. The Company proposes to purchase the Leasehold Interest from the Plan in a one-time transaction for cash. It is represented that the Company will pay the greater of: (a) the fair market value of the Leasehold Interest on the date of the sale, or (b) the Plan's original acquisition cost, plus all costs attributable to the Plan's holding of the Property, through the date of the sale. For purposes of the sale, the original acquisition cost plus holding costs is determined as follows: (original purchase price + aggregate real estate taxes through the date of the sale + all other expenses and fees through the date of the sale) = original acquisition cost plus holding costs. As stated above, through July 8, 1997, the original acquisition cost plus holding costs for the Leasehold Interest was $490,350. Because the Company is required to pay the original acquisition plus all holding costs through the date of the sale and holding costs have continued to accrue since July 8, 1997, the Company will pay the Plan an amount in excess of $490,350 for its Leasehold Interest.

8. The Property was appraised by Stephen A. Rosenthal (Rosenthal), MAI, an independent real estate appraiser certified by the state of California, on August 2, 1996.[2] Rosenthal is a principal in the Sacramento, California, appraisal firm of Ramirez Rosenthal Company.

Rosenthal initially appraised the combined value of the fee simple interest of the Office Complex and underlying land. Applying both the comparable sales and income capitalization methods of appraisal, Rosenthal determined that the fair market value of the fee simple interest of the Office Complex and underlying land was $1,650,000.

In determining the fair market value of the Leasehold, Rosenthal considered the remaining primary term of the Leasehold as well as the two ten year renewal periods. In addition, Rosenthal considered income and expenses related to the ownership of the Leasehold. Based on this analysis and the value of the fee simple interest in the Office Complex and underlying land, Rosenthal determined that the fair market value of the Leasehold was $1,010,000.

Based on Rosenthal's appraisal, the Company represents that the fair market value of the Plan's 16.28% Leasehold Interest is 16.28% of $1,010,000, which equals $164,428.

9. Because the Plan's original acquisition cost plus holding costs exceeds $164,428, which is the fair market value of the Plan's Leasehold Interest, the Company represents that it will purchase the Leasehold Interest from the Plan at a price equal to the Plan's original acquisition cost plus holding costs. Since through July 8, 1997, this amount totaled $490,353, the Company will purchase the Leasehold Interest for $490,353 plus an amount which represents all additional holding costs that have accrued since the July 8, 1997. Payment of such amount is a

[1] This figure represents the Plan's original acquisition plus holding costs through July 8, 1997. Since this date, the Plan's total investment in the Property has continued to increase due to the continuing expenses related to holding the Leasehold Interest.

[2] On August 24, 1998, Rosenthal opined that since the date of the appraisal, there has not been a dramatic change in the quality or character of the locality surrounding the Property and based on a study of recent comparable sales, that the Property has not significantly increased in value.

condition of the exemption proposed herein.

10. The Company represents that the sale transaction will occur as soon as possible after the publication in the **Federal Register** of a notice granting the exemption proposed herein, if granted. The Company represents that the proposed transaction is favorable to the Plan because the sale will be a one-time cash transaction and the Plan will incur no expenses as a result of the sale. In addition, it is represented that the sale is in the best interest of the participants and beneficiaries because the ownership of the Leasehold Interest has resulted in an operating loss to the Plan since 1992 and the Office Complex has had a 44% vacancy rate since 1996.

11. In summary, the Company represents that the proposed transaction satisfies the 408(a) of the Act for the following reasons: (a) the Plan will receive cash for the Leasehold Interest which is the greater of (1) the fair market value of the Leasehold Interest, and (2) the original acquisition cost, plus all attributable holding costs through the date of the sale; (b) the sale will be a one-time cash transaction and the Plan will incur no expenses or commissions related to the sale; and (c) the Plan will divest itself of an investment which has resulted in a loss to the Plan for every year since 1992.

FOR FURTHER INFORMATION CONTACT: Ms. Janet L. Schmidt of the Department, telephone (202) 219–8883. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 10th day of September, 1998.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 98–24799 Filed 9–15–98; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION AGENCY

[Notice 98–118]

Information Collection; Submission for OMB Review, Comment Request

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of agency report forms under OMB review.

SUMMARY: The National Aeronautics and Space Administration has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this proposal should be received on or before October 16, 1998.

ADDRESSES: All comments should be addressed to Ms. Carrie Sorrels, Code S, National Aeronautics and Space Administration, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Carmela Simonson, Office of the Chief Information Officer, (202) 358–1223.

Reports: None.

Title: Grants Proposal Writers and Peer Reviewers Customer Satisfaction Surveys.

OMB Number: 2700–0084.

Type of review: Reinstatement.

Need and Uses: The survey information will be used by NASA to improve the efficiency, quality, and timeliness of its grant process, as well as to strengthen its partnership with external customers.

Affected Public: Not-for-profit institutions, Federal Government.

Number of Respondents: 930.

Responses Per Respondent: 1.

Annual Responses: 248.

Hours Per Request: 15 min.

Annual Burden Hours: 62.

Frequency of Report: On occasion.

Donald J. Andreotta,

Deputy Chief Information Officer (Operations), Office of the Administrator.

[FR Doc. 98–24743 Filed 9–15–98; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION AGENCY

[Notice 98–119]

Information Collection; Submission for OMB Review, Comment Request

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of agency report forms under OMB review.

SUMMARY: The National Aeronautics and Space Administration has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this proposal should be received on or before October 16, 1998.

ADDRESSES: All comments should be addressed to Ms. Darlene Ahalt, Goddard Space Flight Center, Greenbelt, MD.

FOR FURTHER INFORMATION CONTACT: Ms. Carmela Simonson, Office of the Chief Information Officer, (202) 358–1223.

Reports: None.

Title: Application for Volunteer Program.

OMB Number: 2700–0057.

Type of review: Extension.

Need and Uses: The application is used to be considered as a Goddard

Space Flight Center Visitor Center Volunteer.

Affected Public: Individuals or households, Business or other for-profit, Not-for-profit institutions, Farms, Federal Government, State, Local or Tribal Government.

Number of Respondents: 50.

Responses Per Respondent: 1.

Annual Responses: 50.

Hours Per Request: 1 hr.

Annual Burden Hours: 50.

Frequency of Report: On occasion.

Donald J. Andreotta,

Deputy Chief Information Officer (Operations), Office of the Administrator.

[FR Doc. 98–24744 Filed 9–15–98; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities; Proposed Collection; Comment Request

TITLE OF COLLECTION: 1999 National Survey of College Graduates (OMB Control No. 3145–0141).

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: Under the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3501 *et seq.*), and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation (NSF) is inviting the general public or other Federal agencies to comment on this proposed continuing information collection.

FOR FURTHER INFORMATION CONTACT: For further information or for a copy of the collection instruments and instructions contact Ms. Mary Lou Higgs, Acting Clearance Officer, via surface mail: National Science Foundation, ATTN: NSF Reports Clearance Officer, Suite 295, 4201 Wilson Boulevard, Arlington, VA 22230; telephone (703) 306–2063; e-mail mlhiggs@nsf.gov; or FAX (703) 306–0201.

SUPPLEMENTARY INFORMATION:

1. Abstract

The National Survey of College Graduates (NSCG) has been conducted biennially since 1993. In the 1999 NSCG, persons trained and/or working in science and engineering will be contacted. The purpose of this longitudinal study is to provide national estimates on the science and engineering workforce and changes in employment, education and demographic characteristics. The study is one of three components of the Scientists and Engineers Statistical Data System (SESTAT), which produces national estimates of the size and characteristics of the nation's science and engineering population.

The National Science Foundation Act of 1950, as subsequently amended, includes a statutory charge to ''* * * provide a central clearinghouse for the collection, interpretation, and analysis of data on scientific and engineering resources, and to provide a source of information for policy formulation by other agencies of the Federal Government.'' The NSCG is designed to comply with these mandates by providing information on the supply and utilization of the nation's scientists and engineers. The NSCG provides the majority of records into the SESTAT data system. The NSF uses this information to prepare congressionally mandates reports such as Science and Engineering Indicators and Women and Minorities in Science and Engineering. A public release file of collected data, edited to protect respondent confidentiality, will be made available to researchers on CD–ROM and on the World Wide Web.

The Bureau of the Census, as in the past, will conduct the study for NSF. Questionnaires will be mailed in April 1999 and nonrespondents to the mail questionnaire computer assisted telephone interviewing. The survey will be collected in conformance with the Privacy Act of 1974 and the individual's response to the survey is voluntary.

2. Expected Respondents: We will mail the survey to a statistical sample of approximately 40,000 respondents from the 1997 NSCG survey.

3. Burden on the Public: The amount of time to complete the questionnaire may vary depending on an individual's circumstances; however, on average it will take approximately 25 minutes to the complete the survey. We estimated that the total annual burden will be 16,666 hours during the year.

Comments Requested

DATES: Send written comments to NSF on or before November 16, 1998.

ADDRESSES: Submit written comments to Ms. Mary Lou Higgs, Acting Clearance Officer, through surface mail at: National Science Foundation, ATTN: NSF Reports Clearance Officer, Suite 295, 4201 Wilson Boulevard, Arlington, VA 22230; through e-mail to mlhiggs@nsf.gov; or via FAX (703) 306–0201.

SPECIAL AREAS FOR REVIEW: NSF request special review and comments in the following areas:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Foundation, including whether the information will have practical utility;

(b) The accuracy of the Foundation's estimate of the burden of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on those who are to respond.

Dated: September 8, 1998.

Mary Lou Higgs,

Acting NSF Clearance Officer.

[FR Doc. 98–24848 Filed 9–15–98; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope, Availability of Draft NUREG

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability and request for comments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the availability of, and requesting comment on, draft NUREG–1556, Volume 11, ''Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses of Broad Scope,'' dated August 1998.

NRC is using Business Process Redesign techniques to redesign its materials licensing process, as described in NUREG–1539, ''Methodology and Findings of the NRC's Materials Licensing Process Redesign.'' A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. This draft NUREG report is the 11th program-specific guidance developed to support the improved materials licensing process.

It is intended for use by applicants, licensees, and staff and will also be available to Agreement States. This document combines, updates and supersedes the guidance for applicants and licensees previously found in Draft Regulatory Guide DG–0005 dated October 1994. Included in this guidance is a new option for Type A licensees of broad scope to have increased flexibility to make changes in some program areas and revise some procedures previously approved by NRC without amendment of the license.

Draft NUREG–1556, Volume 11, is not intended to be used alone. Because

broad-scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution, etc.), this document frequently refers the user to other more program-specific guidance documents in the NUREG–1556 series. This document takes a more risk-informed, performance-based approach to the information needed to support an application for a license of broad scope. Note that this document is strictly for public comment and is not for use in preparing or reviewing licenses of broad scope until it is published in final form.

DATES: The comment period ends on December 7, 1998. Comments received after that time will be considered if practicable.

ADDRESSES: Submit written comments to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U. S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Hand deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:15 a.m. and 4:30 p.m. on Federal workdays. Comments may also be submitted through the Internet by addressing electronic mail to slm2@nrc.gov.

Those considering public comment may request a free single copy of draft NUREG–1556, Volume 11, by writing to the U.S. Nuclear Regulatory Commission, ATTN: Mrs. Sally L. Merchant, Mail Stop TWFN 9–F–31, Washington, DC 20555–0001. Alternatively, submit requests through the Internet by addressing electronic mail to slm2@nrc.gov. A copy of draft NUREG–1556, Volume 11, is also available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555–0001.

FOR FURTHER INFORMATION CONTACT: Mrs. Sally L. Merchant, Mail Stop TWFN 9–F–31, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–7874; electronic mail address: slm2@nrc.gov.

Electronic Access

Draft NUREG–1556, Volume 11 will be available electronically by visiting NRC's Home Page (http://www.nrc.gov/NRC/nucmat.html) approximately 2 weeks after the publication date of this notice.

Dated at Rockville, Maryland, this 10th day of September, 1998.

For the Nuclear Regulatory Commission.

Frederick C. Combs,

Acting Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 98–24832 Filed 9–15–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Industrial Radiography Licenses

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the completion and availability of NUREG–1556, Volume 2, ''Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Industrial Radiography Licenses,'' dated August 1998.

ADDRESSES: Copies of NUREG–1556, Volume 2 may be obtained by writing to the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402–9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. A copy of the document is also available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC 20555–0001.

FOR FURTHER INFORMATION, CONTACT: Mr. J. Bruce Carrico, Mail Stop TWFN 8–F–5, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–7826.

SUPPLEMENTARY INFORMATION: On September 17, 1997 (62 FR 48904), NRC announced the availability of draft NUREG–1556, Volume 2, ''Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Industrial Radiography Licenses,'' dated August 1997, and requested comments on it. This draft NUREG report was the second program-specific guidance developed to support an improved materials licensing process. The staff considered all of the comments, including constructive suggestions to improve the document, in the preparation of the final NUREG report.

The final version of NUREG–1556, Volume 2, is now available for use by applicants, licensees, NRC license reviewers, and other NRC personnel, and will also be available to Agreement States. It supersedes the guidance for applicants and licensees previously found in Regulatory Guide FC 401–4, ''Guide for the Preparation of Applications for the Use of Sealed Sources and Devices for Performing Industrial Radiography,'' dated October 1984, and in Nuclear Material Safety and Safeguards Policy and Guidance Directive FC 84–15, ''Standard Review Plan for Applications for the Use of Sealed Sources and Devices for Performing Industrial Radiography,'' dated October 1984. This guidance has been prepared to correspond to the new requirements and format established in the revision of 10 CFR Part 34 published in 1997. NUREG–1556, Volume 2, takes a more risk-informed, performance-based approach to licensing industrial radiography and reduces the information (amount and level of detail) needed in support of an application for these devices. This final report should be used in preparing radiography licensing applications. NRC will use this final report in reviewing these applications.

Electronic Access

NUREG–1556, Volume 2, will be available electronically, approximately 1 month after the publication date of this notice, by visiting NRC's Home Page (http://www.nrc.gov) and choosing ''Nuclear Materials,''and then ''NUREG–1556, Volume 2.''

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

Dated at Rockville, Maryland, this 10th day of September, 1998.

For the Nuclear Regulatory Commission.

Frederick C. Combs,

Acting Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 98–24833 Filed 9–15–98; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Notice of Cancellation of Visit

AGENCY: Postal Rate Commission.

ACTION: Notice of cancellation of visit.

SUMMARY: A Commission visit to tour operations and discuss postal issues with several organizations in the Minneapolis, Minnesota area has been cancelled.

DATES: The visit had been scheduled for September 14–16, 1998.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, Postal Rate Commission, Suite 300, 1333 H Street, NW, Washington, DC 20268–0001, (202) 789–6820.

Margaret P. Crenshaw,

Secretary.

[FR Doc. 98–24831 Filed 9–15–98; 8:45 am]

BILLING CODE 7710–FW–M

POSTAL SERVICE

Notice of Meeting

AGENCY: Postal Service.

ACTION: Notice of meeting.

SUMMARY: The U.S. Postal Service and U.S. Department of State will hold a briefing meeting on preparations for the Universal Postal Union (UPU) Council of Administration in October 1998 and the UPU Congress in Beijing in 1999. The purpose of this meeting will be to brief participants on recent developments concerning some of the key issues being examined by the UPU and to gather input on possible proposals and U.S. positions. The agenda of this meeting will include: (1) Status of terminal dues proposals for the Beijing Congress; (2) UPU regulatory issues; (3) questions, exchange of views and discussion.

MEETING DATE AND TIME: Friday, September 25, 2:00–5:00 p.m.

MEETING PLACE: Room 1107, U.S. Department of State, 2201 ''C'' Street NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Cynthia Proctor, (202) 314–7150.

SUPPLEMENTARY INFORMATION: Individuals or organizations with a substantive interest in these issues may request to attend the meeting and join in the discussions. In this regard, entry into the building is controlled. Individuals wishing to attend must send a fax to (202) 314–7160 no later than September 21, 1998, and include the name of the meeting, individual's name, affiliation, social security number and date of birth. One of the following valid photo ID's will be required for admittance. U.S. driver's license with picture, U.S. passport or U.S. government ID (company ID's are no longer accepted by Diplomatic Security). Enter from the ''C'' Street Main Lobby.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 98–24768 Filed 9–15–98; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Sunshine Act Meeting

Notice is hereby given that the Railroad Retirement Board will hold a meeting on September 22, 1998, 9:00 a.m., at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois, 60611. The agenda for this meeting follows:

Portion Open to the Public

(1) Organizational Placement of the Bureau of Quality Assurance
(2) Restructuring Plan for Office of Programs—Assessment and Training Component
(3) Fiscal Year 2000 Budget and Future Budgets
(4) Employer Status Determination—Railroad Ventures, Inc.
(5) Draft Letter to the Office of Management and Budget Regarding Potential Expanded Investment Instruments
(6) Year 2000 Issues

Portion Closed to the Public

(A) Fiscal Year 1999 Performance Appraisal Plans

The person to contact for more information is Beatrice Ezerski, Secretary to the Board, Phone No. 312–751–4920.

Dated: September 11, 1998.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 98–24893 Filed 9–14–98; 11:40 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 23431; 812–11054]

Equity Managers Trust, et al.; Notice of Application

September 10, 1998.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of an application under sections 6(c) and 17(b) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 17(a) of the Act.

SUMMARY OF THE APPLICATION: The order would permit a registered investment company advised by Neuberger&Berman Management Incorporated (''N&B Management'') to purchase certain securities of an investment account managed by N&B Management.

APPLICANTS: Equity Managers Trust, Retirement Benefit Accumulation Plan for Employees of PricewaterhouseCoopers, Savings Plan for Employees and Partners of PricewaterhouseCoopers, Savings Plan for Employees of PricewaterhouseCoopers, and Profit Sharing Plan for Partners of PricewaterhouseCoopers (''Plans'').

FILING DATES: The application was filed on March 3, 1998, and amended on September 8, 1998.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving the applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on October 5, 1998 and should be accompanied by proof of service on the applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants: Equity Managers Trust, 605 Third Avenue, New York, New York 10158; Plans, 3109 Martin Luther King, Jr. Blvd., Tampa, FL, 33607.

FOR FURTHER INFORMATION CONTACT: Mary Kay Frech, Branch Chief, (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549 (telephone (202) 942–8090).

Applicants' Representations

1. Neuberger&Berman Genesis Portfolio (''Portfolio'') is a series of Equity Managers Trust. Equity Managers Trust is an open-end management investment company organized as a New York common law trust and registered under the Act. Neuberger&Berman Genesis Trust (''Fund'') is a series of Neuberger&Berman Equity Trust (''N&B Equity Trust''), an open-end management investment company

organized as a Delaware business trust and registered under the Act.

2. The Portfolio is a ''master fund'' in a master/feeder fund structure. The Fund is a feeder fund that invests all of its assets in the Portfolio. Beneficial interests in the Portfolio are issued solely in private placement transactions to investment companies and other institutional investors. The Fund's shares are publicly offered.

3. The Plans are employee benefit plans subject to the Employee Retirement Income Security Act of 1974 for the employees and/or partners of PricewaterhouseCoopers. Each Plan offers participants the option to invest in a managed account with investment objectives, policies and limitations substantially similar to those of the Portfolio (''Account''). [1] The Plans invest jointly in the Account, which currently holds cash, shares of the Fund, and other securities. As of June 30, 1998, the Plans, through the Account, own 13.8% of the outstanding shares of the Fund, which amounts to 5.1% of the interests in the Portfolio.

4. N&B Management serves as investment adviser of the Portfolio, administrator of the Fund and distributor of the Fund's shares. Neuberger & Berman, LLC (''N&B'') serves as the Portfolio's sub-adviser. The Portfolio's investment managers (''Portfolio Managers'') also manage the Account on behalf of the Plans.

5. The Plans' trustees believe it would be in each Plan's best interests to liquidate the securities held in the Account. Applicants propose that the Portfolio be permitted to purchase the securities in the Account that the Portfolio Managers deem desirable for investment by the Portfolio, in exchange for cash (''Proposed Transaction''). [2] The purchase price will be the securities' ''independent current market price'' on the date of the transaction, determined in accordance with rule 17a–7(b) under the Act. No brokerage commission, fee or other remuneration will be paid by any party in connection with the Proposed Transaction. Applicants state that the Proposed Transaction is consistent with the investment objectives, policies and limitations of the Portfolio, as recited in its registration statement and reports filed under the Act. All of the securities in the Account that the Portfolio proposes to purchase are listed on a national securities exchange or are traded on the Nasdaq stock market, and the Portfolio currently has positions in each of those securities.

6. The Plans presently intend to invest the cash proceeds from the Proposed Transaction in shares of the Fund. If the investment takes place as proposed, the Account will be dissolved and units in the Account will be exchanged for shares in the Fund most likely on a same-day basis. Each Plan will have its own account on the books of the Fund's transfer agent and the Plans will no longer retain a custodian to hold their assets.

7. On October 23, 1997, the board of trustees of Equity Manager Trust (''Board'') including all of the independent trustees, voted to approved the terms of the Proposed Transaction. The Board reviewed, among other factors, the securities to be purchased, the method by which they would be valued, the size of the Portfolio's current position in each stock under consideration, the size of the Portfolio's position in the stock (if the transaction were consummated), and information on the total market capitalization and average weekly trading volume of each stock. The Board concluded that the Proposed Transaction is in the best interests of the Portfolio and its interest holders.

8. The Proposed Transaction also has been authorized by each Plan's trustees, who are independent of N&B and its affiliates, and the trustees have agreed in principal to invest the cash proceeds in shares of the Fund. N&B provided the Plans' trustees with a current prospectus of the Fund and a written statement disclosing the fees to be received by N&B Management, the terms of the Proposed Transaction, and other relevant factors.

9. Applicants intend to structure the Proposed Transaction as an exchange of securities for cash, rather than having the Plan exchange the assets in the Account for shares of the Fund, because of the master-feeder structure of the Portfolio and the Fund. In addition, the Plans intend to rely on a Department of Labor exemption, which has been interpreted as providing exemptive relief only with respect to cash transactions.

10. Applicants believe that the Proposed Transaction will benefit the Portfolio's interest holders and the Plans' participants. Applicants submit that an increase in the Portfolio's assets from the Proposed Transaction will enable the Portfolio to realize economies of scale that should reduce its operating expenses. The Proposed Transaction will also allow applicants to avoid the brokerage commissions that applicants otherwise would incur if the Plans sold the stocks in the Account on the open market and the Portfolio, as it received cash from the Plans' investment in the Fund, bought investment securities on the open market.

Applicants' Legal Analysis

1. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such a person, acting as principal, from selling any security to, or purchasing any security from the company. Section 2(a)(3) of the Act defines an ''affiliated person'' of another person to include (a) any person that owns 5% or more of the outstanding voting securities of such other person, (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote by such other person, (c) any person directly or indirectly controlling, controlled by or under common control with, such other person, and (d) if such other person is an investment company, any investment adviser of the company.

2. Applicants believe that the Portfolio and the Plans may be deemed to be affiliated persons because they share a common investment adviser. Applicants also believe that the Portfolio and the Plans may be deemed to be affiliated persons because the Plans (through the Account) own 13.8% of the outstanding shares of the Fund, which amounts to 5.1% of the interests in the Portfolio. As a result, applicants believe that the Portfolio's purchase of securities from the Plans is prohibited by section 17(a) of the Act.

3. Rule 17a–7 exempts certain purchase and sale transactions otherwise prohibited by section 17(a) if an affiliation exists solely by reason of having a common investment adviser, common directors, and/or common officers, provided that certain requirements are met. The relief provided by rule 17a–7 is not available for the Proposed Transaction because the Plans' ownership (through the Account and the Fund) of 5.1% of the Portfolio may create an affiliation ''not solely by reason of'' having a common investment adviser, common directors, and/or common officers.

4. Section 17(b) of the Act provides that the SEC may exempt a transaction from the provisions of section 17(a) if the terms of the Proposed Transaction, including the consideration to be paid, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policy of each registered investment company

[1] The Account is an entry on the books of the Plans' custodian and has no separate legal existence.

[2] The term ''Proposed Transaction'' refers to either a single purchase or a series of purchases.

concerned and with the general purposes of the Act. Section 6(c) authorizes the Commission to exempt persons or transactions from the provisions of the Act to the extent that such exemptions are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the Act.

5. Applicants submit, for the reasons discussed below, that their request satisfies these standards. Applicants believe that compliance with rule 17a–7(a)–(f) will ensure that the Proposed Transaction is effected on terms that are fair and reasonable and do not involve overreaching. Applicants believe that because the Proposed Transaction involves a purchase of readily marketable securities for cash and because the Proposed Transaction has been reviewed and approved by the Board, there is no danger that any affiliated person will benefit at the expense of the Portfolio and its interest holders.

Applicants' Condition

Applicants agree that the order granting the requested relief will be subject to the following condition:

The proposed Transaction will comply with the terms of rule 17a–7(a) through (f).

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–24814 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following open meeting during the week of September 21, 1998.

An open meeting will be held on Wednesday, September 23, 1998, at 10:00 a.m.

The subject matter of the open meeting scheduled for Wednesday, September 23, 1998, at 10:00 a.m., will be:

Consideration of whether to adopt an amendment to Rule 102(e) of the Commission Rules of Practice clarifying the Commission's standard for determining when accountants engage in ''improper professional conduct.''

FOR FURTHER INFORMATION CONTACT. Michael J. Kingin, Associate Chief Accountant, Office of the Chief Accountant at (202) 942–0890.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: September 14, 1998.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–24916 Filed 9–14–98; 12:45 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40419; File No. SR–CBOE–98–35]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to Floor Brokerage Subsidies

September 9, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 [2] thereunder, notice is hereby given that on July 27, 1998, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new rule that would allow market-makers in a trading crowd to subsidize the activity of floor brokers who represent orders in that crowd. The proposed rule would also allow market-makers to determine to subsidize the execution of orders from the Exchange's public customer limit order book. Set forth below is the text of the proposed rule.

* * * * *

(The entire rule is new.)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Chicago Board Options Exchange, Inc. Rules

Chapter II—Organization and Administration

Part C—Dues, Fees, and Other Charges; Market-Maker Surcharge for Brokerage

Rule 2.40

(a) Definitions.

(i) Stationary Floor Broker. A Stationary Floor Broker (''SFB'') in a particular option class is a floor broker (A) who has established a business in the trading crowd for that class of accepting and executing orders for members or registered broker-dealers and (B) who transacted at least 80% of his orders for the previous month in the trading crowd at which that option class is traded.

(ii) Resident Market-Maker. A Resident Market-Maker in a particular class of options is a market-maker who transacted at least 80% of his market-maker contracts in option classes traded in the trading crowd where the particular option class is traded in the prior calendar month.

(iii) ORS Orders. For purposes of this Rule, an ORS order is an order that is (A) sent over the Exchange's Order Routing System, (B) given an ORS identification number and (C) not an order of the firm for which the SFB acts as a nominee or for whom the SFB has registered his membership.

(iv) Standard OBO Rate. The Standard OBO Rate is any rate for OBO floor brokerage established by the Exchange for the particular equity option class traded on the Exchange floor.

(b) Generally.

The Resident Market-Makers for a particular option class may vote, as set forth in paragraph (d) of this Rule, to impose a fee on a per contract basis for every contract traded by every market-maker, whether in-person or by order, in that option class during the period for which the fee is instituted. This fee will be collected by the Exchange and used to reimburse the Exchange to the extent the market-makers vote to reduce the Exchange's book rate pursuant to paragraph (g) of this Rule. Any amount remaining after the Exchange has been reimbursed will be paid to every SFB who executed an ORS Order in that option class during the relevant period of time. To the extent more than one SFB executed ORS Orders during the relevant period, this amount remaining shall be paid to the SFBs on a pro rata basis based on the number of ORS contracts executed by the respective SFBs during the period. The fee likely will be assessed after the end of the

month in which transactions on which the fee was based occurred.

(c) Time Period.

The fee shall be instituted for a minimum period of one month. The fee voted upon shall remain effective until the next vote is held.

(d) Vote.

(i) Any Resident Market-Maker may recommend a fee amount by the Friday prior to the vote or by any other time and date required by the OBO. The vote of the Resident Market-Makers to institute the fee shall take place at the station where the applicable option class is traded on the Tuesday of expiration week, or on any other day selected by the OBO for that option class. The Order Book Official (''OBO'') shall provide 24 hour notice of the time and date of the vote to the trading crowd if the vote is to be held at a different time or on a different day. The OBO shall determine how the vote shall be conducted. Any Resident Market-Maker personally present at the trading station when the vote is conducted may vote on the amount of the fee to be assessed for the next period.

(ii) Each Resident Market-Maker's vote shall be weighted in accordance with that Market-Maker's percentage of the contracts traded in the relevant option class during the six calendar months prior to the month in which the vote is taken. For example, the vote of a Market-Maker that traded 5% of the contracts in the previous month will be counted five times as much as the vote of a Market-Maker that traded 1% of the contracts in that options class over the previous six calendar months. In the case of a class that has not traded for six months, the weighting shall be determined in accordance with the respective number of trades for the period of time the option class has traded. For a class that has not traded at all, all Resident Market-Maker's votes shall be weighted equally.

(iii) Any fee amount that receives a majority of the votes cast by weight shall be the fee effective for the following calendar month. If any fee amount does not receive a majority by weight on the first ballot, the OBO may conduct subsequent ballots with the proposed fees receiving the most votes by weight or may solicit Resident Market-Makers for other proposed fee amounts.

(e) Option Classes.

The appropriate Floor Procedure Committee may specify those option classes on which Resident Market-Makers may vote to assess a fee pursuant to paragraph (d) of this Rule.

(f) Floor Brokerage Commission.

Although any SFB who executes ORS Orders in the crowd will be paid the appropriate fee, each SFB may charge any commission rate that floor broker so desires.

(g) Book Brokerage Rates.

The Resident Market-Makers for a particular option class may vote to reduce the Exchange's OBO brokerage rate for that option class pursuant to the terms of the vote in paragraph (d). If the Resident Market-Makers vote to reduce the OBO brokerage rate the Exchange will make the appropriate filing as required by the Exchange Act. To the extent the Resident Market-Makers vote to lower the rate below the Standard OBO Rate, the market-makers who trade that option class shall reimburse the Exchange for the difference pursuant to any fee instituted in paragraph (b). If the Exchange determines on its own to reduce the OBO brokerage rate for a particular class below the Standard OBO Rate the market-makers will not be responsible for reimbursing the Exchange.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Many options traded on the CBOE floor are traded in crowds in which the quotes are established in a competing market-maker system. The Exchange believes the competitive market-maker system has served to provide deep and liquid markets and extremely competitive quotes to the benefit of the Exchange's customers throughout the twenty-five year history of the Exchange. The Exchange has learned, however, that in recent years it has become increasingly difficult for the floor brokers who service customer orders in the Exchange's market-maker crowds to compete in brokerage rates against options' specialists at other exchanges in multiply-traded classes.

Unlike the situation in market-maker crowds, specialists control both the agency and principal functions on other exchanges. As a result, these specialists have the luxury of lowering their brokerage rates to induce firms to send them the firm's order flow. These specialists can still make a comfortable living, even while they reduce their brokerage rates below a level at which the activity could be provided economically as an independent venture, through the income produced from the principal part of the business. The stationary floor brokers on the CBOE floor, however, do not have the ability to reduce their rates to compete with these specialists and still survive, because (unlike these specialists on other exchanges) they have no dealer profits. In some cases, these floor brokers have had to rely on the superior service provided by the CBOE market-maker system to attract order flow even in situations where their rates may be higher than those charged by specialists on other exchanges. In order to allow the Exchange's stationary floor brokers to compete better against other exchange specialists without sacrificing the many advantages inherent in having a number of option classes trade in the competing market-maker crowds, the Exchange has determined to allow its market-makers to provide a subsidy to the floor brokers to provide them the ability to lower their rates and still earn an acceptable level of income.

a. Generally

The proposed rule would allow certain market-makers in a trading crowd to vote to impose a fee on a per contract basis for every contract traded by every market-maker, whether by person or by order, in a particular option class. This fee will be collected by the Exchange and will be used for two purposes. First, the amount collected will be used to reimburse the Exchange to the extent the market-makers vote to reduce the rate charged by the Exchange to execute Order Book Official (''OBO'') orders. The amount paid the Exchange will be the amount of the Standard OBO Rate minus the rate voted on by the market-makers multiplied by the number of contracts executed by market-makers, in person or by order. Any remaining amount of the subsidy collected will then be paid to the stationary floor broker as an inducement for that floor broker to reduce his brokerage rates. The Exchange believes the proposed rule will allow the Exchange's market-maker crowds to compete effectively for order flow against specialists from other exchanges by allowing the brokerage

rates to be reduced to competitive levels. It should be noted that the stationary floor broker would be entitled to charge whatever brokerage rate he feels appropriate, but it is expected that the floor broker will consider the extent to which his business is being subsidized by the market-makers in the crowd in making that determination.

Generally, there is only one stationary floor broker in a trading crowd. In some cases, where there is more than one stationary floor broker in a trading crowd, the amount remaining after the Exchange has been reimbursed will be paid to the stationary floor brokers on a pro rata basis based on the number of Order Routing System (''ORS'') Orders executed by each floor broker. For the sake of ease of administration, the fee likely will be assessed after the end of the month in which transactions on which the fee was based occurred.

b. Definitions

Proposed new Rule 2.40(a)(i) defines the category of brokers who will be entitled to receive part of the market-maker subsidy as a Stationary Floor Broker (''SFB''). An SFB in a particular option class is a floor broker (A) who has established a business in the trading crowd for that class of accepting and executing orders for members or registered broker-dealers, and (B) who transacted at least 80% of his orders for the previous month in the trading crowd at which that option class is traded. The limitations in the definition are designed to ensure that those floor brokers who have made a commitment to the particular option class and who are willing to accept orders from a wide variety of market participants are the ones who will benefit from the subsidy. It is these floor brokers whose reduced brokerage rates for a class of options will be most likely to attract or retain order flow in that class, which will be of benefit to the market-makers in the trading crowd for that class of options.

Proposed new Rule 2.40(a)(ii) defines that category of market-makers who will be entitled to vote on the market-maker surcharge and on any reduction from the Standard OBO Rate as a Resident Market-Maker. A Resident Market-Maker is defined as a market-maker in a particular option class who transacted at least 80% of his market-maker contracts in option classes traded in the trading crowd where the particular option class is traded in the prior calendar month. The limitation in this definition ensures that those market-makers who have made a commitment to fulfilling their market-maker obligations in the relevant trading crowd are the ones who determine to what extent they will be willing to compete to attract business to the trading crowd.

Proposed new Rule 2.40(a)(iii) defines the types of orders for which SFBs can earn a subsidy. An ORS Order, for purposes of this rule, is an order sent over the Exchange Order Routing System and given an ORS identification number and that is not an order of the firm for whom the SFB acts as a nominee or for whom the SFB has registered his membership. The Exchange decided to make the determination on the amount of a subsidy an SFB receives by reference to the number of ORS contracts that SFB executed because the rate the SFB charges for ORS orders is most likely to be the rate which will attract the most order flow. Non-ORS orders—such as spreads, large telephone orders, and complex or contingent orders—may require more effort and expertise from the floor broker and are not as sensitive to rates as to level of service. In addition, the Exchange determined not to allow ORS orders executed by an SFB on behalf of the firm for whom the SFB is a nominee or for whom he has registered his membership because these orders will be executed by the SFB by virtue of the relationship and not by virtue of the rate charged.

c. Option Classes/Time Period

The Exchange has determined to allow the appropriate Floor Procedure Committee to determine on which classes of options the market-makers will have the authority to vote to assess a fee and to reduce the OBO brokerage rate. The Exchange believes that it is likely that the program will be started in a few options classes initially to determine the effects of the program on allowing the market-maker crowds to compete with specialists from other options exchanges. Over time it is expected that the program may be expanded more broadly across the floor. Any subsidy agreed to be paid by the market-makers would have to be in effect for at least one month in order not to disrupt normal Exchange billing and accounting procedures.

d. Voting Procedures

Proposed new Rule 2.40(d)(i) requires that the vote of the Resident Market-Makers to institute a fee shall take place in the crowd where the applicable option class is traded and the vote will be conducted by the OBO in that option class. The normal date and time set for the vote will be 8:15 a.m. on the Tuesday of expiration week. Expiration week is chosen because that is the week when the attendance is generally highest. The OBO, however, can set a different time and/or date by providing a 24-hour notice of the different time and/or date. Any Resident Market-Maker in the crowd at the time of the vote will be entitled to vote on the amount of the fee or on any reduction in the OBO brokerage rate for the next calendar month. The votes shall be weighted in accordance with the number of contracts traded by the particular market-maker in the relevant option class in the six calendar months prior to the vote. For example, the vote of a Resident Market-Maker that traded 5% of the contracts in the previous six calendar months will be counted five times as much as the vote of a Market-Maker that traded 1% of the contracts in that options class over the previous six calendar months. In the case of a class that has not traded for at least six months, the weighting shall be determined in accordance with the respective number of trades for the period of time the option class has traded. For a class that has not traded at all, all Resident Market-Makers' votes shall be weighted equally.

Any proposed fee amount that receives a majority of the weighted votes shall become effective for the next calendar month. If any fee amount does not receive a majority by weight on the first ballot, the OBO may conduct subsequent ballots by seeking approval of the proposed fees receiving the most votes by weight or by seeking approval for other fee amounts proposed by Resident Market-Makers. Similarly, the Resident Market-Makers may vote to reduce the OBO brokerage rate to the rate receiving the majority of the weighted votes being effective for the next calendar month. Again, the OBO may conduct subsequent votes if no proposed OBO brokerage rate received the majority of the weighted votes. If the Exchange determines to reduce the OBO brokerage rate for a particular class of options to a new lower Standard OBO Rate, the market-makers will not be responsible for reimbursing the Exchange.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)([3] of the Act in general and further the objectives of Section 6(b)(5)[4] in particular in that they are designed to promote just and equitable principles of trade and to protect investors and the public interest.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change is anticipated to enhance the ability of market-makers to compete with the other exchanges for order flow.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organizations consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of CBOE. All submissions should refer to File No. SR–CBOE–98–35 and should be submitted by October 7, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–24819 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40422; International Series Release No. 1156; File No. SR–EMCC–98–07]

Self-Regulatory Organizations; Emerging Markets Clearing Corporation; Order Granting Accelerated Approval of a Proposed Rule Change To Require Members To Maintain a Pre-Billing Deposit

September 9, 1998.

On July 24, 1998, Emerging Markets Clearing Corporation (''EMCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–EMCC–98–07) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] Notice of the proposal was published in the **Federal Register** on August 14, 1998.[2] No comment letters were received. For the reasons discussed below, the Commission is granting accelerated approval of the proposed rule change.

I. Description

Under the rule change, EMCC will require each member to maintain on deposit with EMCC an amount equal to three times the member's average monthly EMCC bill (''pre-bill amount''). The purpose of the pre-bill amount is to provide EMCC with additional operating cash. The average monthly bill will be based on a member's three most recent monthly EMCC bills, excluding all pass-through charges. If a member does not have a three month billing history (*e.g.*, a new member), EMCC will estimate the member's average monthly bill in calculating the pre-bill amount. Members will continue to be billed monthly based on their actual use of EMCC's services.

EMCC will recalculate the pre-bill amount quarterly. If a member's recalculated pre-bill amount is greater than its prior pre-bill amount, the amount of such difference will appear on the member's next monthly bill as an additional charge. Conversely, if a member's recalculated pre-bill amount is less than its prior pre-bill amount, the amount of such difference will appear on the member's next monthly bill as a credit.

II. Discussion

Section 17A(b)(3)(D) of the Act[3] requires that the rules of a clearing agency provide for the equitable allocation of reasonable dues, fees, and other charges among its participants. The Commission believes that the proposed rule change is consistent with EMCC's obligations under Section 17A(b)(3)(D) because the pre-bill amount will be calculated based on each member's use of EMCC's services. In addition, the rule change provides for quarterly recalculation of the pre-bill amount, which should help ensure that each member's pre-bill amount accurately reflects the current level of its use of EMCC's services.

EMCC has requested that the Commission approve the proposed rule change prior to the thirtieth day after publication of the notice of the filing. The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the publication of notice because such approval will allow EMCC to collect the pre-bill amounts promptly which should increase its liquidity resources.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act[4] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–EMCC–98–07) be and hereby is approved on an accelerated basis.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–24815 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

[5] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 40311 (August 7, 1998), 63 FR 43737.

[3] 15 U.S.C. 78q–1(b)(3)(D).

[4] 15 U.S.C. 78q–1.

[5] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40424; File No. SR–NASD–98–68]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to the Submission of Trade Reports in PORTAL-Designated Securities to the Automated Confirmation and Transaction Service

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 8, 1998, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association'') through its wholly owned subsidiary the Nasdaq Stock Market, Inc. (''Nasdaq'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to interpret the definition of ''ACT Eligible Security'' in Rule 6110(a) of the rules of the NASD for the Automated Confirmation Transaction Service (''ACT'') to include all securities designated as PORTAL securities pursuant to the Rule 5320 Series of the PORTAL Market Rules to the extent transactions in such PORTAL-designated securities are voluntarily submitted to ACT solely for reconciliation, comparison, and/or clearance and settlement.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Since 1983, NASD Rule 11180 has required each member that is a participant in a registered clearing agency to subscribe to and reconcile all eligible transactions through the Trade Acceptance and Reconciliation Service (''TARS''), a system operated by Nasdaq. TARS is an on-line reconciliation facility that allows both parties to a trade, through the Nasdaq Workstation, to reconcile breaks on contract sheets from their clearing corporation with respect to over-the-counter (''OTC'') and exchange-listed stocks. None of the trade information submitted to TARS is disseminated to the public in any manner. TARS has been offered as an independent service, distinct from ACT. ACT is the Nasdaq-operated system used by members to compare trades and to submit trades to clearance and settlement at The Depository Trust Company (''DTC''). Pursuant to the rules for Reporting Transactions in Over-the-Counter Equity Securities in the Rule 6600 Series, members are obligated to transmit through ACT last sale reports of transactions in OTC equity securities for which real-time trade reporting is not otherwise required, which results in public dissemination of last sale reports for these transactions. Thus, unlike TARS, ACT includes a function for the public dissemination of last sale reports.

Because of low reconciliation activity in TARS, Nasdaq determined to integrate TARS functionality into ACT and eliminate the TARS service. Pursuant to proposed rule change SR–NASD–98–47, Nasdaq eliminated TARS by deleting NASD Rule 11180 and amended ACT rules to integrate the TARS functionality into ACT. This proposed rule change was effective upon filing on July 9, 1998, in accordance with Section 19(b)(3)(A) of the Act.[3] Pursuant to proposed rule change SR–NASD–98–47, Nasdaq proposes to implement the elimination of TARS as of September 8, 1998. Thereafter, transactions in OTC equity securities, that are not otherwise required to be submitted to ACT under the Rule 6600 Series, may voluntarily be submitted to ACT solely for the purpose of taking advantage of the reconciliation, comparison and/or clearing functions in ACT.

Nasdaq has been advised by a number of members that they have been using the TARS service for reconciliation of transactions in equity securities designated as PORTAL securities under the Rule 5320 Series of the PORTAL Market Rules. The PORTAL Market is a system operated by Nasdaq for securities sold in a private placement by an issuer under the exemption from registration provided by Section 4(2) of the Securities Act of 1933 (''1993 Act''),[4] that qualify for resale by investors under Rule 144A under the 1993 Act.[5] Designation of a security issue as a PORTAL security qualifies the issue for book-entry clearance and settlement at DTC. Thus, all PORTAL securities are depository eligible. Recently, members have requested advice as to whether they can continue to voluntarily submit trade details with respect to transactions in equity PORTAL-eligible securities, previously submitted through TARS, into ACT for purposes of reconciliation, comparison, and/or clearance only.

Currently, the definition of ''ACT Eligible Security'' in Rule 6110(a) of the ACT Rules does not directly reference PORTAL, privately placed, or restricted securities. Thus, PORTAL-designated securities are not specifically excluded by this definition from treatment as an ACT eligible security.[6] Nasdaq is proposing to temporarily interpret the definition of ''ACT Eligible Security'' to include all PORTAL-designated securities to the extent those securities are voluntarily submitted to ACT solely for reconciliation, comparison, and/or clearance and settlement. Nasdaq has initiated modifications and procedures related to ACT that will inhibit the ability of any person entering a transaction in a security with a CUSIP number for a PORTAL security from designating the transaction as a ''reportable trade,'' thereby preventing last sale reports for PORTAL-designated securities from being publicly disseminated. ACT will treat any entry involving a PORTAL-designated security as one submitted solely for reconciliation, comparison, and/or clearance and settlement purposes.

Finally, in light of the limited use of ACT for PORTAL-designated securities,

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 15 U.S.C. 77(d)(2).

[5] 17 CFR 230.144A.

[6] The definition of ''ACT Eligible Security'' does include, among other securities, all OTC Equity Securities as defined in Rule 6600. The definition of ''OTC Equity Security'' in Rule 6610(d) does specifically exclude all restricted securities, as defined in Rule 144(a)(3) under the 1993 Act, and PORTAL-designated securities. Nasdaq is not proposing to amend or interpret this latter definition as such an amendment would subject all PORTAL-designated securities to the mandatory 90 second ''reporting'' requirements of the Rule 6600 Series, and would result in the public dissemination of last sale information for such transactions.

it is Nasdaq's position that the submission of trade details in PORTAL-designated securities to ACT will not subject these transactions to SEC fees pursuant to Section 31 of the Act,[7] as PORTAL-designated securities are not subject to ''prompt last sale trade reporting'' as that term is used for the purposes of Section 31 fee assessment.

2. Statutory Basis

The NASD believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[8] which requires, among other things, that the Association's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The NASD believes that the proposed rule change is wholly consistent with the purposes of the Act in that it will encourage members to submit trade details of transactions in PORTAL-designated securities to the Association through ACT for reconciliation, comparison, and clearance and settlement purposes and will, thereby, provide the Association with trade details regarding such transactions and facilitate clearance and settlement in such securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Nasdq has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the NASD and, therefore, has become effective pursuant to Section 19(b)(3)(A)(i) of the Act[9] and subparagraph (e)(1) of Rule 19b-4 thereunder.[10] At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.[11] Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to No. SR–NASD–98–68 and should be submitted by October 7, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–24816 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

[7] 15 U.S.C. 78ee.

[8] 15 U.S.C. 78*o*–3.

[9] 15 U.S.C. 78s(b)(3)(A)(i).

[10] 17 CFR 240.19b–4(e)(1).

[11] In reviewing this proposed rule change, the Commission has considered its impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40418; File No. SR–PCX–98–38]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Equity Trading Halts Due to Extraordinary Market Volatility

September 9, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 4, 1998, as amended on August 31, 1998, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to codify its rules relating to trading halts in equity securities due to extraordinary market volatility.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b–4 (1991).

[3] On August 31, 1998, the PCX an amendment with the Commission, requesting that the Commission treat the filing as a ''non-controversial'' rule filing pursuant to Rule 19b–4(e)(6), 17 CFR 240.19b–4(e)(6). The amendment also clarified the background to the PCX's existing circuit breaker policy and proposed rule change, and made technical corrections to the filing. *See* Letter from Michael Pacileo, Staff Attorney, PCX to Joshua Kans, Attorney, Division of Market Regulation, Commission, dated August 31, 1998. The Commission deems the proposal filed upon receipt of the August 31, 1998 amendment.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The Exchange is proposing to codify its current policy of imposing trading halts as quickly as practicable whenever the New York Stock Exchange (''NYSE'') and other equity markets have suspended trading due to extraordinary market volatility. The Exchange most recently restated its market closing policy in April 1998, in conjunction with the NYSE's and other exchanges' amendments to their circuit breaker rules.[4]

Circuit Breakers are coordinated cross-market trading halts that are intended to help avoid systematic breakdown when a severe one-day market drop of historic proportions prevents the financial markets from operating in an orderly manner. The securities and futures market introduced circuit breakers to offer investors an opportunity to assess information and positions when the markets experience a severe, rapid decline.

In 1988, in response to the October 19, 1987 market drop, the Commission approved various exchanges' circuit breaker proposals, along with the PCX's and National Association of Securities Dealers' (''NASD'') circuit breaker policy statements. The circuit breaker proposals were intended to provide market participants with an opportunity during a severe market decline to reestablish an equilibrium between buying and selling interest in a more orderly fashion. In October 1997, the first circuit breakers were triggered due to a decline of 554 points on the Dow Jones Industrial Average (''Dow''). This triggering of the circuit breakers when the markets were operating smoothly prompted the markets to re-evaluate the operation and function of circuit breakers. In January 1998, as a result of the events of October 1997, several exchanges adopted interim changes to the circuit breaker rules.[5] Subsequently, the markets agreed to the current uniform circuit breaker rule, which the PCX proposes to codify.[6]

The PCX proposes to codify its Circuit Breaker trigger levels for a one-day decline of 10 percent, 20 percent, and 30 percent of the Dow, to be calculated at the beginning of each calendar quarter, using the average closing value of the Dow for the previous month to establish specific point values for the quarter. Each trigger will be rounded to the nearest 50 points.[7]

Before 11:00 a.m.,[8] the halt for a 10 percent decline will be one hour. At or after 11:00 a.m. but before 11:30 a.m., the halt will be for one-half hour. If the 10 percent trigger value is reached at or after 11:30 a.m., the market will not halt at the 10 percent level and will continue trading.

The halt for a 20 percent decline will be two hours if triggered before 10:00 a.m. At or after 10:00 a.m. but before 11:00 a.m., the halt will be for one hour. If the 20 percent trigger value is reached at or after 11:00 a.m., trading will halt for the remainder of the day. If the market declines by 30 percent, at any time, trading will be halted for the remainder of the day.

(2) Basis

The Exchange believes that this proposal is consistent with Section 6(b) of the Act,[9] in general, and Section 6(b)(5),[10] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) does not significantly affect the protection of investors or the public interest; (2) does not imposed any significant burden on competition; and (3) does not become operative for 30 days from August 31, 1988, the date on which the filing was amended to reflect the noncontroversial status of this rule change,[11] it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(e)(6) thereunder.

At any time within 60 days of the August 31, 1998 amendment of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.[13] Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, N.W.,

[4] *See* Securities Exchange Act Release No. 39846 (April 9, 1998), 63 FR 18477 (April 15, 1998).

[5] *See* Securities Exchange Act Release No. 39852 (January 26, 1998), 63 FR 5408 (February 2, 1998) (order granting accelerated approval of proposed rule changes by NYSE, American Stock Exchange (''AMEX''), Boston Stock Exchange (''BSE''), Chicago Stock Exchange (''CHX'') and Philadelphia Stock Exchange (''PHLX'')). The proposed rule changes became effective on February 2, 1998, and were approved on a pilot basis until April 30, 1998.

[6] *See* Securities Exchange Act Release No. 39846 (April 9, 1998), 63 FR 18477 (April 15, 1998) (approving proposed rule changes by NYSE, AMEX, BSE, CHX, PHLX and NASD).

[7] For example, if the average of the Dow closing values for the previous month is 7700, 10% of such average would be 770; this number would be rounded to the nearest 50 points to create a circuit breaker trigger level of 750 points. In addition, if a trigger level is midway between two points, it will be rounded down, *e.g.,* 825 would be rounded to 800, and 875 would be rounded to 850.

[8] All time references are to Pacific Time.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] The Commission waived the five-day prefiling requirement for ''noncontroversial'' rule changes under Rule 19b–4(e)(6), 17 CFR 240.19b–4(e)(6), because the Commission had an opportunity to review the proposal when the Exchange originally submitted it on August 4, 1998.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] In reviewing the proposal, the Commission has considered its impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

Washington, D.C. 25049. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All submissions should refer to File No. SR–PCX–98–38 and should be submitted by October 7, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–24817 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40412; File No. SR–PCX–98–27]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Pacific Exchange, Inc. Relating to the Automatic Execution of Option Orders

September 8, 1998.

I. Introduction

On June 12, 1998, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend PCX Rule 6.87 governing the operations of the Exchange's Automatic Execution System. On July 14, 1998, the PCX filed with the Commission Amendment No. 1 to the proposed rule change.[3] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 3, 1998.[4] The Commission received no comments regarding the proposal. This order approves the proposal as amended.

II. Description of the Proposal

Presently, orders entered via the Exchange's Member Firm Interface (''MFI'') are delivered to one of three destinations: (a) to the Exchange's Automatic Execution System for options trading (''Auto-Ex''), where they are automatically executed at the disseminated bid or offering price; (b) to Auto-Book, which maintains non-marketable limit orders based on limit price and time receipt; or (c) to a Member Firm's default destination, a particular firm booth or remote entry site, if the order fails to meet the eligibility criteria necessary for using either Auto-Ex or Auto-Book or if the Member Firm requests such default for its orders.[5]

The Exchange now proposes to adopt new PCX Rule 6.87(d),[6] which would provide that the Exchange's Options Floor Trading Committee (''OFTC'') may designate electronic orders in an option issue to receive automatic executions at prices reflecting the National Best Bid or Offer (''NBBO'').

The proposal would allow the OFTC to designate, for an option issue, that an order will default for manual representation by a floor broker in the trading crowd if the order would be executed at a price that is more than one trading increment away from the PCX market price[7] The proposal also would permit the OFTC to designate, for an option issue, that if the NBBO is crossed (*e.g.*, 6⅛ bid, 6 asked) or locked (*e.g.*, 6 bid, 6 asked), then customer orders to buy or sell the series would default for manual representation in the trading crowd. Under the proposal, however, the Exchange would maintain the flexibility to require automatic executions on the Exchange when the NBBO is locked or crossed. Such action may be appropriate, for example, when there is a large influx of electronic orders and a fair and orderly market would be better served by a reduction in the number of orders. In such situations, public customers would receive very favorable prices on their orders.

III. Discussion

After careful review, the Commission finds that the proposal rule change is consistent with the requirements of the Act. In particular, the Commission believes the proposal is consistent with Section 3(f)[8] and Section 6(b)(5)[9] of the Act. Section 6(b)(5) requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade and to protect investors and the public interest.

By automating the execution of eligible retail orders for equity options, the proposal should help to ensure that investors receive prompt, automatic execution of Auto-Ex options orders at the best available prices, even if those prices are being quoted in a market other than the Exchange. This proposal should minimize the delay inherent in manually handling orders in this circumstance, and thereby reduce the risk to investors that, as a result of an adverse move in the market while their orders are being manually handled, they may receive an inferior execution or none at all.

Moreover, the proposal is consistent with Section 3(f) of the Act because it should help to promote competition for dually listed options among options exchanges by helping to ensure that investors receive an automatic execution at the NBBO regardless of whether that quote originated on the PCX or on another exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (SR–PCX–27), as amended, is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

[FR Doc. 98–24818 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Michael D. Pierson, Senior Attorney, Regulatory Policy, Exchange, to Ken Rosen, Attorney, Division of Market Regulation, Commission, dated July 13, 1998 (''Amendment No. 1'').

[4] Securities Exchange Act Release No. 40263 (July 24, 1998) 63 FR 41312.

[5] *See* Securities Exchange Act Release No. 27633 (January 18, 1990) 55 FR 2466 (January 24, 1990); Securities Exchange Act Release No. 39970 (May 7, 1998) 63 FR 26662 (May 13, 1998).

[6] PCX Rules 6.87 governs the operation of Auto-Ex. Currently, only non-broker/dealer customer orders for up to ten option contracts (or 20 option contracts, depending on the option issue) are eligible to be executed on Auto-Ex. *See* PCX Rule 6.87. Moreover, Auto-Ex is designed to prevent executions at prices inferior to prices being concurrently disseminated in other marketplaces in multiply-traded issues. When Auto-Ex prevents an automatic execution from occurring because it would trade through a better price on another market, the order will default either to a member firm booth or to a hand-held terminal in the trading crowd (depending on the member firm's instruction). *See* Letter from Michael D. Pierson, Senior Attorney, Regulatory Policy, Exchange, to Kenneth Rosen, Attorney, Division, Commission, dated August 27, 1998. Thereafter, the order could be represented manually.

[7] The Commission recently approved a similar proposal by the Chicago Board Options Exchange. *See* Securities Exchange Act Release No. 40096 (June 16, 1998) 63 FR 34209 (June 23, 1998).

[8] In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40420, File No. SR–PHLX–98–23]

September 9, 1998.

Self-Regulatory Organizations: Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. to Amend By-Law Article XI, § 11–1—Appeals; Article XII, § 12–4—Application; and Article XV, § 15–3—Disposition of Proceeds of Sale of Membership

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 18, 1998, the Philadelphia Stock Exchange, Inc. (''PHLX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change as described in Items, I, II, and III below, which Items have been prepared by the Exchange.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange seeks to amend By-Law Article XI, § 11–1—Appeals; Article XII, § 12–4—Application; and Article XV, § 15–3—Disposition of Proceeds of Sale of Membership. The Exchange has proposed a By-Law amendment to Article XV to permit the Board of Governors to determine the validity and amount of claims asserted against a membership. Additionally, the Exchange proposes to amend Article XI and Article XII to provide that an adverse Admissions Committee decision may be appealed to the Board. The text of the proposed rule change is available at the Office of the Secretary, the PHLX and the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the PHLX included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Propose Rule Change

1. Purpose

The PHLX has proposed a By-Law amendment to Article XV, § 15–3, Disposition of Proceeds of Sale of Membership, to permit the Board of Governors, rather than the Arbitration Committee or a panel thereof, to determine the validity and amount of claims asserted against a membership pursuant to the specified order of claims enumerated in the By-Laws. This proposed By-Law amendment, as recommended by the Arbitration and Executive Committees of the Board, seeks to conform the By-Law with procedures adopted by other registered national securities exchanges[4] and provides for Board oversight of seat proceeds disposition.

Additionally, the Exchange proposes to amend Article XI, § 11–1, Appeals, and Article XII, § 12–4, Application, to provide that an adverse Admissions Committee decision be appealed to the Board. These proposed amendments seek to conform the By-Laws with procedures adopted by other exchanges wherein appeals are taken to the Board or heard by a panel of the Board subject to ratification, such as CBOE Rule 19.5 and American Stock Exchange, Inc., Constitution, Article IV, § 1(g). Thus, the proposal creates a right of appeal from Admissions Committee decisions.

2. Statutory Basis

The proposed rule change is consistent with Section 6 of the Act[5] in general, and in particular, with Section 6(b)(5)[6] in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, as well as to protect investors and the public interest by providing Board oversight of the disposition of seat proceeds and Admissions Committee appeals.

B. Self-Regulatory Organization's Statement on Burden on Competition

The PHLX does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were received in response to Circulars 98–56 and 98–67, which were distributed to all members and participants of the PHLX.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the PHLX consents, the Commission will:

(A) By order approve such proposed rule change, or,

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

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[1] 15 U.S.C. 78s(b)(1) (1994).

[2] 17 CFR 240.19b–4 (1997).

[3] The proposal was originally submitted on June 24, 1998, however, the PHLX failed to include the circulars as required by Form 19b–4. *See* Form 19b–4, 3 Fed. Sec. L (CCH) ¶ 33,351. The Exchange subsequently submitted Amendment No. 1 that included the circulars and made technical changes to the proposed rule language. *See* Letter from Murray L. Ross, Vice President and Secretary, PHLX, to Michael Walinskas, Deputy Associate Director, Division of Market Regulation (''Division''), Commission, dated August 17, 1998 (''Amendment No. 1''). In addition, the PHLX agreed to additional technical changes to its proposed rule language to accurately reflect the differences between the proposed rule language and the PHLX's current rule language. Telephone conversation between Murray L. Ross, Vice President and Secretary, PHLX and Karl Varner, Attorney, Division, Commission, on September 1, 1998.

[4] *See* Chicago Board Options Exchange (''CBOE'') Rule 3.15 and New York Stock Exchange, Inc. Constitution, Article II, Sec. 11.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the PHLX's principal offices. All submissions should refer to File No. SR–PHLX–98–23 and should be submitted by October 7, 1998.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–24820 Filed 9–15–98; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before October 16, 1998. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and OMB Reviewer, Victoria Wassmer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–6629.

SUPPLEMENTARY INFORMATION:

Title: Application forms for 8(a) Program.

Form No.: 1010A, 1010B, 1010C.

Frequency: On Occasion.

Description of Respondents: 8(a) Companies.

Annual Responses: 33,000.

Annual Burden: 177,000.

Dated: September 10, 1998.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 98–24788 Filed 9–15–98; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3103; Amendment #5]

State of Iowa

In accordance with information received from the Federal Emergency Management Agency dated August 31, 1998, the above-numbered Declaration is hereby amended to include Decatur and Union Counties in the State of Iowa as a disaster area due to damages caused by severe storms, tornadoes, and flooding beginning on June 13, 1998 and continuing through July 15, 1998. This declaration is further amended to extend the deadline for filing applications for physical damages as a result of this disaster to September 14, 1998.

In addition, applications for economic injury loans from small businesses located in the contiguous county of Mercer in the State of Missouri may be filed until the specified date at the previously designated location. All other counties contiguous to the above-named primary counties have been previously declared.

All other information remains the same, i.e., the deadline for filing applications for economic injury is April 2, 1999.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: September 3, 1998.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 98–24792 Filed 9–15–98; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3126]

State of North Carolina

As a result of the President's major disaster declaration on August 27, 1998, and amendments thereto on September 1 and 2, I find that the following counties in the State of North Carolina constitute a disaster area due to damages caused by Hurricane Bonnie beginning on August 25, 1998 and continuing through September 1, 1998: Beaufort, Bertie, Bladen, Brunswick, Camden, Carteret, Chowan, Columbus, Craven, Cumberland, Currituck, Dare, Duplin, Greene, Hyde, Jones, Lenoir, Martin, New Hanover, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Pitt, Robeson, Sampson, Tyrrell, Washington, and Wayne. Applications for loans for physical damages as a result of this disaster may be filed until the close of business on October 26, 1998, and for loans for economic injury until the close of business on May 27, 1999 at the address listed below or other locally announced locations:

Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308

In addition, applications for economic injury loans from small businesses located in the following contiguous counties and independent cities may be filed until the specified date at the above location: Edgecombe, Gates, Halifax, Harnett, Hertford, Hoke, Johnston, Moore, Northampton, Scotland, and Wilson Counties in North Carolina; Dillon, Horry, and Marlboro Counties in South Carolina; and the Independent Cities of Chesapeake, Suffolk, and Virginia Beach in Virginia. The interest rates are:

	Percent
Physical Damage:	
HOMEOWNERS WITH CREDIT AVAILABLE ELSEWHERE	6.875
HOMEOWNERS WITHOUT CREDIT AVAILABLE ELSEWHERE	3.437
BUSINESSES WITH CREDIT AVAILABLE ELSEWHERE	8.000
BUSINESSES AND NON-PROFIT ORGANIZATIONS WITHOUT CREDIT AVAILABLE ELSEWHERE	4.000
OTHERS (INCLUDING NON-PROFIT ORGANIZATIONS) WITH CREDIT AVAILABLE ELSEWHERE	7.125
For Economic Injury:	
BUSINESSES AND SMALL AGRICULTURAL COOPERATIVES WITHOUT CREDIT AVAILABLE ELSEWHERE	4.000

The number assigned to this disaster for physical damage is 312608. For economic injury the numbers are 998400 for North Carolina, 998500 for South Carolina, and 998600 for Virginia.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

[7] 17 CFR 200.30–3(a)(12).

Dated: September 3, 1998.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 98–24791 Filed 9–15–98; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3085; Amendment #1]

State of South Dakota

In accordance with information received from the Federal Emergency Management Agency, the above-numbered Declaration is hereby amended to include Brown, Clark, Codington, Day, Marshall, Roberts, and Spink Counties in the State of South Dakota as a disaster area due to damages caused by flooding, severe storms, and tornadoes, and to establish the incident period for this disaster as beginning on April 25, 1998 and continuing through June 22, 1998. This declaration is further amended to extend the deadline for filing applications for physical damages as a result of this disaster to September 21, 1998.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the previously designated location: Beadle, Deuel, Edmunds, Falk, Grant, Hamlin, Hand, Kingsbury, and McPherson Counties in South Dakota, and Big Stone and Traverse Counties in Minnesota. All other counties contiguous to the above-named primary counties have been previously declared.

All other information remains the same, i.e., the deadline for filing applications for economic injury is March 1, 1999.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: September 2, 1998.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 98–24789 Filed 9–15–98; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3125; Amendment #1]

State of Texas

In accordance with notices from the Federal Emergency Management Agency dated August 30 and 31, 1998, the above-numbered Declaration is hereby amended to include Kinney, Maverick, Real, Uvalde, and Webb Counties in the State of Texas as a disaster area due to damages caused by Tropical Storm Charley. This declaration is further amended to establish the incident period for this disaster as beginning on August 22, 1998 and continuing through August 31, 1998. In addition, applications for economic injury loans from small businesses located in the following contiguous counties in the State of Texas may be filed until the specified date at the previously designated location: Bandera, Dimmit, Duval, Frio, Jim Hogg, Kerr, LaSalle, McMullen, Medina, Zapata, and Zavala. Any counties contiguous to the above-named primary counties and not listed herein have been previously declared.

All other information remains the same, i.e., the deadline for filing applications for physical damage is October 24, 1998, and for economic injury the deadline is May 26, 1999.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: September 4, 1998.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 98–24793 Filed 9–15–98; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3123; Amendment #1]

State of Wisconsin

In accordance with information received from the Federal Emergency Management Agency, the above-numbered Declaration is hereby amended to include Racine County, Wisconsin as a disaster area due to damages caused by severe storms and flooding, and to establish the incident period for this disaster as beginning on August 5, 1998 and continuing through August 15, 1998.

In addition, applications for economic injury loans from small businesses located in the contiguous county of Kenosha in the State of Wisconsin may be filed until the specified date at the previously designated location. All other counties contiguous to the above-named primary county have been previously declared.

All other information remains the same, i.e., the deadline for filing applications for physical damage is October 11, 1998, and for economic injury the deadline is May 12, 1999.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: September 2, 1998.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 98–24790 Filed 9–15–98; 8:45 am]

BILLING CODE 8025–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Industry Sector Advisory Committee on Small and Minority Business (ISAC–14)

AGENCY: Office of the United States Trade Representative.

ACTION: Notice that the October 5, 1998, meeting of the Industry Sector Advisory Committee on Small and Minority Business will be held from 9:15 a.m. to 3:00 p.m. The meeting will be closed to the public from 12:00 noon to 3:00 p.m. and open to the public from 9:15 a.m. to 12:00 noon.

SUMMARY: The Industry Sector Advisory Committee on Small and Minority Business will hold a meeting on October 5, 1998 from 9:15 a.m. to 3:00 p.m. The meeting will be closed to the public from 12:00 noon to 3:00 p.m. The meeting will include a review and discussion of current issues which influence U.S. trade policy. Pursuant to Section 2155(f)(2) of Title 19 of the United States Code, I have determined that this meeting will be concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any trade agreement and other matters arising in connection with the development, implementation and administration of the trade policy of the United States. The meeting will be open to the public and press from 9:15 a.m. to 12:00 noon when trade policy issues will be discussed. Attendance during this part of the meeting is for observation only. Individuals who are not members of the committee will not be invited to comment.

DATES: The meeting is scheduled for October 5, 1998, unless otherwise notified.

ADDRESSES: The meeting will be held at the Department of Commerce, Room 4830, located at 14th and Constitution Avenue, NW, Washington, D.C., unless otherwise notified.

FOR FURTHER INFORMATION CONTACT: Bill Daley, Office of the United States Trade Representative, (202) 395–6120.

Pate Felts,

Assistant U.S. Trade Representative for Intergovernmental Affairs and Public Liaison.

[FR Doc. 98–24801 Filed 9–15–98; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF TRANSPORTATION

Office of The Secretary

Aviation Proceedings, Agreements Filed During the Week Ending September 4, 1998

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. Sections 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST–98–4396.

Date Filed: August 31, 1998.

Parties: Members of the International Air Transport Association.

Subject: PTC1 0082 dated August 25, 1998 Longhaul Expedited Resos r1–6 Intended effective date: October 1, 1998.

Docket Number: OST–98–4397.

Date Filed: August 31, 1998.

Parties: Members of the International Air Transport Association.

Subject: PTC1 0083 dated August 25, 1998 r1–2—Within South America Expedited Resos, PTC1 0084 dated August 25, 1998 r3–18—Caribbean Expedited Resos, PTC1 0085 dated August 25, 1998 r19—Within South America Expedited Resos, PTC1 Fares 0029 dated August 25, 1998 Tables. Intended effective date: October 1, 1998.

Docket Number: OST–98–4398.

Date Filed: August 31, 1998.

Parties: Members of the International Air Transport Association.

Subject: PTC12 CAN–EUR 0033 dated August 18, 1998—Canada-Europe Resolutions r1–33, PTC12 CAN–EUR 0034 dated August 25, 1998 Minutes, PTC12 CAN–EUR Fares 0013 dated August 18, 1998 Tables.

Intended effective date: January 1, 1999.

Docket Number: OST–98–4408.

Date Filed: September 2, 1998.

Parties: Members of the International Air Transport Association.

Subject: PTC31 S/CIRC 0048 dated June 9, 1998—South Pacific Resos r1–29, PTC31 S/CIRC 0049 dated June 12, 1998 Minutes, PTC31 S/CIRC 0050 dated June 12, 1998 Correction.

(Accompanying tables were published in Memorandum PTC31 S/CIRC Fares 0017 and filed in Docket OST–98–3898 with the expedited portion of the agreement.)

Intended effective date: October 1, 1998.

Dorothy W. Walker,

Federal Register Liaison.

[FR Doc. 98–24759 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of The Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending September 4, 1998

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–98–4401.

Date Filed: August 31, 1998.

Due Date for Answers, Conforming Applications, or Motions to Modify Scope: September 28, 1998.

Description: Application of Itapemirim Transportes Aereos, S.A. pursuant to 49 U.S.C. Section 41302 and Subpart Q, applies for a foreign air carrier permit authorizing scheduled foreign air transportation of property and mail between a point or points in Brazil, on the one hand, and the co-terminal points Los Angeles, California; New York, New York (JFK), Atlanta, Georgia; and Miami, Florida, via intermediate points, subject to Part 212 of the charter regulations.

Dorothy W. Walker,

Federal Register Liaison.

[FR Doc. 98–24760 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOCKET No. OST–98–4146]

Request for Comments on Implementation of the Transportation Efficiency Act for the 21st Century (TEA–21)

AGENCY: Office of the Secretary, DOT.

ACTION: Notice; Request for Comments.

SUMMARY: The Department of Transportation will maintain a public docket for comments from its partners and customers on the implementation of the recently enacted Transportation Efficiency Act for the 21st Century (TEA–21). The docket is in conjunction with a series of TEA–21 outreach sessions. This Notice supplements the previous announcement of the docket in the **Federal Register** on July 28, 1998.

DATES: Submit comments on or before November 22, 1998.

ADDRESSES: Your written comments must be signed and refer to docket number OST–98–4146. Send them to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 7th Street, SW., Washington, DC 20590–0001. All comments received will be available for public examination at this address between 10 a.m. and 5 p.m., ET. Monday through Friday, except Federal Holidays. Persons who wish notification of the receipt of their comments must include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT: Walter Finch, Special Assistant to the Associate Deputy Secretary and Director, Office of Intermodalism S–3, U.S. Department of Transportation, 400 7th Street SW., Washington, DC 20590. Tel: (202) 366–8015.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. DOT Dockets, Room PL–401, by using the universal resource locator (URL): http://dms.dot.gov. It is available 24 yours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the **Federal Register** electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the **Federal Register**'s home page at: http://www.nara.gov/nara/fedreg and the Government Printing Office's database at: http://www/access.gpo.gov/nara.

The Transportation Equity Act for the 21st Century (TEA–21) was signed into law on June 9, 1998. Prior to implementation, the US DOT is consulting with its partners and customers through a series of TEA–21 outreach sessions/meetings. This docket supplements the outreach sessions/meetings by offering the public a way to submit written comments either in the place of attendance at the outreach

sessions/meetings or to offer more extensive comments than can easily be accommodated orally. Comments in the docket will be forwarded to the element of the Department responsible for the relevant provisions of TEA–21. Comments will then be considered in decisionmaking on how to implement TEA–21. If the Department decides to pursue implementation of a provision of TEA–21 by issuing regulations, the Department will then initiate formal rule making under the Administrative Procedures Act.

For more information about the TEA–21 outreach sessions and meetings, please visit our website at http://www.fhwa.dot.gov/tea21/outreach.htm or contact Walter Finch at the address and phone number under the heading **FOR FURTHER INFORMATION CONTACT.** For the text of TEA–21 (PL 105–178) as well as a summary and fact sheets on its provisions, please visit our website at http://www.fhwa.dot.gov/tea21/legis.htm.

The outreach sessions and public meetings consist of five National listening sessions, seven One-DOT Conferences, and a series of topic-specific information exchange meetings. The TEA–21 outreach sessions and meetings are scheduled between July 20, 1998 and mid-November, 1998.

The US DOT encourages all interested parties to submit written comments through November 22 on any TEA–21 provision. Since the docket will contain comments on many different provisions of TEA–21, It is important that you identify the specific TEA–21 provision(s) you are commenting on.

Authority: 49 U.S.C. 322 and PL 105–178.

Issued in Washington, DC, on September 10, 1998.

Walter P. Finch,

Special Assistant, Office of Intermodalism, Department of Transportation.

[FR Doc. 98–24761 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG 1998–4436]

Agency Information Collection Activities Under OMB Review

AGENCY: Coast Guard, DOT.

ACTION: Request for comments.

SUMMARY: The U.S. Coast Guard has submitted for emergency processing an information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act. The ICR concerns safety approval of cargo containers. OMB approval of the ICR was requested by August 28, 1998.

DATES: Comments must reach the Coast Guard on or before November 16, 1998.

ADDRESSES: You may mail comments to the Docket Management Facility, (USCG–1998–4436), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW, Washington, DC 20590–0001; or deliver them to room PL–401, located on the Plaza Level of the Nassif Building at the same address between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

The Docket Management Facility maintains the public docket for this document. Comments will become part of this docket and will be available for inspection or copying at room PL–401, located on the Plaza Level of the Nassif Building at the same address between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at http://dms.dot.gov. Copies of the complete Information Collection Request are available through this docket on the Internet at http://dms.dot.gov and also from Commandant (G–SII–2), U.S. Coast Guard Headquarters, room 6106, (Attn: Barbara Davis), 2100 Second Street, SW, Washington, DC 20593–001. The telephone number is 202–267–2326.

FOR FURTHER INFORMATION CONTACT: For questions on this document, contact Barbara Davis, Office of Information Management, 202–267–2326. For questions on this docket, contact Dorothy Walker, Chief, Dockets, 202–366–9330.

Request for Comments

The Coast Guard encourages interested persons to submit written comments. Persons submitting comments should include their names and addresses, identify this document (USCG–1998–4436) and the specific Information Collection Request (ICR) to which each comment applies, and give the reason(s) for each comment. Please submit all comments and attachments in an unbound format no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

Information Collection Requests

1. *Title:* Safety Approval of Cargo Containers.

OMB Control Number: 2115–0094.

SUMMARY: The information collection requires owners and manufacturers of cargo containers to submit information and keep records to make it possible for the Coast Guard or its appointed agents to conduct the approval process. The reporting requirements are necessary to provide the Coast Guard the information it needs to approve new equipment and designs. The recordkeeping requirements are necessary to assist the Coast Guard in its inspections of containers following approval.

Need: This collection of information addresses the reporting and recordkeeping requirements for containers in 49 CFR Parts 450–453. These rules are necessary because the U.S. is signatory to the International Convention for Safe Containers (CSC). These rules prescribe only the minimum requirements of the CSC.

Respondents: Container owners; container manufacturers; organizations to which the Coast Guard delegates its approval authority.

Frequency: On occasion.

Burden Estimate: The estimated burden is 71,504.85 hours annually.

Dated: September 10, 1998.

S.A. Richardson,

Acting Director of Information and Technology.

[FR Doc. 98–24851 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Proposed Advisory Circular 25–XX, Certification of Transport Airplane Electrical Equipment Installations

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Availability of Proposed Advisory Circular (AC) 25–XX and request for comments.

SUMMARY: This notice announces the availability of and requests comments on a proposed advisory circular (AC) which provides methods acceptable to the Administrator for showing compliance with the type of certification requirements for transport airplane electrical systems and equipment installations. This notice is necessary to give all interested persons an opportunity to present their views on the proposed AC.

DATES: Comments must be received on or before January 14, 1999.

ADDRESSES: Send all comments on proposed AC to: Federal Aviation Administration, Attention: John McGraw, Manager, Airplane and Flightcrew Interface Branch, ANM–111,

Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW, Renton, WA 98055–4056. Comments may be inspected at the above address between 7:30 a.m. and 4:00 p.m. weekdays, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Katherine Burks, Transport Standards Staff, at the address above, telephone (425) 227–2114.

SUPPLEMENTARY INFORMATION:

Comments Invited

A copy of the draft AC may be obtained by contacting the person named above under **FOR FURTHER INFORMATION CONTACT** Interested persons are invited to comment on the proposed AC by submitting such written data, views, or arguments as they may desire.

Commenters should identify AC 25–XX, and submit comments, in duplicate, to the address specified above. All communications received on or before the closing date for comments will be considered by the Transport Standards Staff before issuing the final AC.

Discussion

This advisory circular applies to Part 25 of the Federal Aviation Regulations for transport category airplanes for which a new, amended, or supplemental type certificate is requested. The policy extracts contained in the AC are presented in order to provide guidelines which can help in understanding and resolving certification issues or making approval decisions. In the past, advisory and guidance information applicable to transport airplane electrical systems and equipment installations has been formally published within ACs. However in many instances policy has been developed and applied to specific certification projects without formal publication. This policy was documented in the form of policy memorandums, issue papers which were distributed to the FAA Aircraft Certification Offices, or in the form of letters sent to commercial companies, other U.S. government agencies, U.S. Congressional representatives, or foreign certification and airworthiness authorities. In many instances this information was not organized in a way that allowed easy access. This AC is intended to document existing policy so that the public and FAA personnel have access to this information. The excerpts from memoranda and letters provided in this AC represent historical views of regulations and requirements which may have evolved since the issue of policy in the extract, and may be applicable to a specific airplane model depending on the certification basis. The applicant and the cognizant certificating authority are advised to check and ensure, at the earliest practical moment, that a specific policy extract applies to any specific airplane type certification programs.

Issued in Renton, Washington, on September 8, 1998.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 98–24853 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory; Committee Meeting on Emergency Evacuation Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) to discuss emergency evacuation issues.

DATES: The meeting will be held on October 8, 1998, at 10 a.m. Arrange for oral presentations by October 2, 1998.

ADDRESSES: The meeting will be held at the Fiesta Inn Conference Center, Prescott Room, 2100 South Priest Drive, Tempe, AZ.

FOR FURTHER INFORMATION CONTACT: Effie M. Upshaw, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue, SW, Washington, DC 20591, Telephone (202) 267–7626, FAX (202) 267–5075.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III), notice is given of an ARAC meeting to be held on October 8, 1998, at the Fiesta Inn Conference Center, Prescott Room, 2100 South Priest Drive, Tempe, AZ.

The agenda will include:

- Opening remarks.
- Review of a new harmonization task on access to type III exits and clarification of issues relative to the task.
- Report on Performance Standards Working Group activities.

Attendence is open to the public, but will be limited to space available. The public must make arrangements by October 2, 1998, to present oral statements at the meeting. Written statements may be presented to the committee any time by providing 25 copies to the Assistant Executive Director for Emergency Evacuation Issues or by providing copies at the meeting. In addition, sign and oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on September 10, 1998.

Joseph A. Hawkins,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 98–24852 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–98–4370]

Transportation and Community and System Preservation Pilot Program—Implementation of the Transportation Equity Act for the 21st Century

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice; request for comments on program implementation in FY 2000 and beyond; request for letters of intent for FY 1999 planning and implementation grants.

SUMMARY: This document provides implementation guidance on section 1221 of the Transportation Equity Act for the 21st Century (TEA–21), Pub. L. 105–178, 112 Stat. 107 (1998), which establishes the Transportation and Community and System Preservation Pilot Program (TCSP). The TCSP provides funding for planning grants, implementation grants, and research to investigate and address the relationship between transportation and community and system preservation. The States, local governments, and metropolitan planning organizations (MPOs) are eligible for discretionary grants to plan and implement strategies which improve the efficiency of the transportation system, reduce environmental impacts of transportation, reduce the need for costly future public infrastructure investments, ensure efficient access to jobs, services and centers of trade, and examine development patterns and identify strategies to encourage private sector development patterns which achieve these goals.

Through the TCSP, the States, local governments, and MPOs will implement

and evaluate current preservation practices and activities that support these practices, as well as develop new, innovative approaches. Funding for the TCSP is $20 million in FY 1999 and $25 million per year for FY's 2000 through 2003. The FHWA seeks public comments from all interested parties regarding implementation of the TCSP in FY 2000 and beyond, and letters of intent from potential grantees for FY 1999 funding.

DATES: Comments on program implementation must be received on or before November 16, 1998. Requests for letters of intent for FY 1999 planning and implementation grants must be received on or before November 16, 1998.

ADDRESSES: Your signed, written comments on program implementation must refer to the docket number appearing at the top of this document and you must submit the comments to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

Submit letters of intent to the FHWA Division Office in the State of the applicant. The addresses and telephone numbers are provided in an attachment to this notice.

FOR FURTHER INFORMATION CONTACT: Susan B. Petty, Office of Environment and Planning, HEP–20, (202)366–6577; or S. Reid Alsop, Office of the Chief Counsel, HCC–31, (202)366–1371; Federal Highway Administration, 400 Seventh Street SW., Washington D.C. 20590. The voice mail telephone number for the TCSP is (800)488–6034.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. DOT Dockets, Room PL–401, by using the universal resource locator (URL): http://dms.dot.gov. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office Electronic Bulletin Board Service at (202)512–1661. Internet users may reach the **Federal Register**'s home page at: http://www.nara.gov/fedreg and the Government Printing Office's database at: http://www.access.gpo.gov/nara.

Background

Section 1221 of the TEA–21 establishes the TCSP. The Department of Transportation's Strategic Plan (1997–2003) includes a series of goals related to safety, mobility and access, economic growth and trade, enhancement of communities and the natural environment, and national security. The TCSP pilot program relates to each of these goals and provides funding for planning grants, implementation grants, and research to investigate and address the relationship between transportation and community and system preservation. By funding innovative activities at the neighborhood, local, metropolitan, State and regional level, the program is intended to increase the knowledge of the costs and benefits of different approaches to integrating transportation investments, community preservation, land development patterns and environmental protection. It will enable communities to investigate and address the relationship among these many factors.

This notice includes three sections: Section I—Notice of Program Implementation; Section II—Requests for Letters of Intent for FY 1999; and Section III—Request for comments.

Section I: Notice of Program Implementation

Introduction

The TCSP provides funding for planning grants, implementation grants and research to investigate and address the relationship between transportation and community and system preservation. States, local governments and metropolitan planning organizations (MPOs) are eligible for discretionary grants to plan and implement strategies which improve the efficiency of the transportation system, reduce environmental impacts of transportation, reduce the need for costly future public infrastructure investments, ensure efficient access to jobs, services and centers of trade, and examine development patterns and identify strategies to encourage private sector development patterns which achieve these goals. Through the TCSP, States, local governments, and MPOs will implement and evaluate current preservation practices and activities that support these practices, as well as develop new, innovative approaches.

The activities and research funded under this program will develop, implement and evaluate transportation strategies that support transportation and community and system preservation practices. The program will demonstrate transportation strategies that incorporate the short- and long-term environmental, economic, and social equity needs of communities. Examples of current preservation practices include policies to direct spending to high growth regions; establishment of urban growth boundaries to guide metropolitan expansion; and designation of green corridors that provide access to major highway corridors for efficient and compact development. In addition, it may include preservation practices that are necessary to implement transit oriented development plans, traffic calming measures and other coordinated transportation and community and system preservation activities. The size, scope and number of grants funded under TCSP will be dependent on the proposals received. The FHWA anticipates that in the first year of the program there may be 20 to 30 grants.

Outreach and Cooperation

The DOT is establishing this program in cooperation with other Federal agencies, State, regional, and local governments. To prepare the initial design and implementation of this program, and to review and evaluate grant applications for the Secretary of Transportation, the FHWA is administering this program and has established a working group with representatives from the Federal Transit Administration, Federal Railroad Administration, Research and Special Programs Administration/Volpe Center, Office of the Secretary of Transportation, and the Environmental Protection Agency. The working group is gathering input through this notice and through meetings with stakeholders conducted as part of DOT's outreach activities following the passage of the TEA–21. For ongoing input into the development and priorities for the program, the working group is considering workshops with grantees and stakeholders and further **Federal Register** notices to announce subsequent rounds of grant funding. In addition, section 5107 of TEA–21 requires the establishment of an advisory board under the Surface Transportation-Environment Cooperative Research Program. This board of scientists, engineers, and State and local agencies may, when it is established in the future, provide another opportunity to gather ongoing input for the development of the program.

Research Program

The TCSP includes a comprehensive research program to investigate the relationships between transportation, community preservation, and the environment, and to investigate the role of the private sector in shaping such relationships. The research program also includes monitoring and analysis of projects carried out under the grant program.

The goal of the research program is to build a knowledge base of work in this field that will enable State, regional and local government agencies, the private sector and neighborhood groups, through transportation activities, to help shape communities that meet current and long term environmental, social equity, and economic goals. With coordination and input from its partners and stakeholders, the FHWA will identify and initiate needed research to support the purposes of the TCSP. The research program is integral to TCSP, and it will support and complement the activities conducted through planning and implementation grants. Likewise, applied research activities that may be a part of a grant activity would be beneficial to the research program.

This notice requests comments and suggestions on the research program but does not solicit specific research proposals. The DOT anticipates that most of the TCSP will be allocated for planning and implementation grants and that limited funding will be available for research. The research may be conducted through cooperative agreements with organizations, contract support, or through State, local and MPO grants.

The DOT proposes to concentrate research activities in five areas:

1. Synthesis of existing research and knowledge. Initial work will focus on gathering information about existing and ongoing transportation projects related to the development of community preservation activities which could include for example, the Maryland Smart Growth initiative, and the Land Use, Transportation and Air Quality (LUTRAQ) program in Portland, Oregon. The synthesis will highlight critical issues that will be particularly useful to agencies developing grant proposals in the early years of the TCSP.

2. Identification of gaps in our knowledge base and the strategies for closing them. The synthesis of existing knowledge will also be used to identify those areas where further research and information is required and to determine the tools needed by practitioners at the local and regional level to implement programs which support transportation investments that foster community and transportation system preservation.

3. An evaluation component for each grant project and an overall program evaluation. In addition to the evaluation of each planning and implementation project that receives TCSP funding, the FHWA will also conduct an overall program evaluation combining the results of the planning and implementation grants and the research program to help set the strategic direction and future priorities for the TCSP.

4. Development of needed tools and methodologies to support decision makers. Transportation-related tools and analytical techniques will be enhanced to help support the State and local decision makers in taking a longer term view and balancing economic, social equity, and environmental goals.

5. Effective coordination and dissemination of results, tools and information developed by the program. An important measure for the success of TCSP is the extent to which the results and best practices from the pilot program are used effectively by government agencies, the private sector, and others. Under the research component of TCSP, the FHWA will establish outreach, technical assistance, and other means to share and implement the results elsewhere.

Planning and Implementation Grants Program

The TCSP will provide grants for planning activities and for implementation activities. Planning grants are intended to help States, local governments, and MPOs begin to initiate transportation, community and system preservation activities in partnership with non-governmental organizations. Implementation grants are intended to support States, local governments, and MPOs (and their non-governmental partners) that have already initiated community preservation programs and policies. These grants will fund innovative transportation and planning activities, which are carried out as part of a cooperative, continuing and comprehensive transportation planning process, to meet these goals.

Activities eligible for TCSP funding include activities eligible for Federal highway and transit funding (title 23, U.S.C., or Chapter 53 of title 49, U.S.C.) or other activities determined by the Secretary to be appropriate. However, where possible, grants will be awarded for new and innovative activities that are eligible but remain unfunded under the current Federal-aid program.

Eligible Recipients

State agencies, metropolitan planning organizations and units of local governments that are recognized by a State are eligible recipients of TCSP grant funds. This would include towns, cities, public transit agencies, air resources boards, school boards, and park districts but not neighborhood groups or developers. Non-governmental organizations that have projects they wish to see funded under this program are encouraged to partner with an eligible recipient as the project sponsor.

An MPO may be both a project sponsor and endorse other activities proposed and submitted by a local government within its metropolitan boundary. An MPO or State may consider packaging related activities for submittal as one larger grant request.

Purposes and Criteria of the TCSP Grant Program

Activities funded under TCSP must address and integrate each of the purposes of the program listed below. If a proposal does not address one or more purposes, the applicant must clearly state why each purpose was not addressed. Priority will be given to those proposals which clearly and comprehensively meet and integrate the greatest number of purposes and are likely to produce successful results. How well proposed projects achieve each of these purposes will be a principal criterion in selecting proposals for funding.

Grant proposals must address how proposed activities will meet all of the following:

1. Improve the efficiency of the transportation system.

Proposals for TCSP activities should identify, develop and evaluate new strategies and measures of transportation efficiency that are based on maximizing the use of existing community infrastructure, such as highways, railroads, transit systems and the built environment. Performance measures should include a focus on people and access rather than cars or goods carried, and services provided rather than miles traveled.

2. Reduce the impacts of transportation on the environment.

Proposals for TCSP activities should explore the long term direct and indirect social, economic and environmental impacts of transportation investments on the natural and built environment. Performance measures should relate the results of individual activities to the larger community and regional environment and the transportation system.

3. Reduce the need for costly future public infrastructure.

Proposals for TCSP activities should describe how they will reduce the need for costly future public infrastructure investment and/or create tools and techniques to measure these savings over the life cycle of the activities. Performance measures should include projected life cycle savings obtained through avoided future investments or maintenance.

4. Ensure efficient access to jobs, services and centers of trade.

Proposals for TCSP activities should clearly demonstrate how they improve efficient, affordable access to jobs, services and centers of trade, including for disadvantaged groups. This could also include the use of new technologies to reduce the need to travel. Performance measures should include improved access to jobs and services, and improved freight movements.

5. Encourage private sector development patterns.

Proposals for TCSP activities should identify effective strategies to encourage private sector investments that result in land development patterns that help meet the goals of this pilot program. Performance measures should demonstrate and monitor changes in development patterns and private sector investment trends or opportunities resulting from TCSP-related activities.

Priorities for all Grants

In addition to the items listed above, applications for planning and implementation grants will also be evaluated based on a number of factors:

a. A demonstrated commitment of non-Federal resources. Although matching funds are not required, priority will be given to projects which leverage non-Federal funds and take advantage of in-kind contributions such as maintenance agreements, land donations and volunteer time.

b. An evaluation component (see later discussion). This should include a description of activities that will be undertaken to disseminate the results and lessons of the project to peers, especially neighboring or nearby agencies and jurisdictions.

c. An equitable distribution of grants with respect to a diversity of populations. The DOT will also be ensuring the equitable distribution of funds to geographic regions, including an appropriate mix of rural and urban activities.

d. The involvement and participation of non-traditional partners in the project team. Such partners might include public utility operators, social services agencies, community groups, environmental organizations, non-profit organizations, public health agencies, private land development organizations and real estate investors.

Additional Planning Grant Information

Planning assistance under the TCSP is intended to provide financial resources to States and communities to explore integrating their transportation programs with community preservation and environmental activities. Grants will be awarded for planning activities that will achieve this integration, meet the purposes of the program described above and are innovative. This may include, for example, public and private involvement activities; improving conditions for bicycling and walking; better and safer operation of existing roads, signals and transit systems; development of new types of transportation financing and land-use alternatives; development of new programs and tools to measure success; and the creation of new planning tools and policies necessary to implement TCSP-related initiatives.

Additional Implementation Grant Criteria

Implementation grants under the TCSP are intended to provide financial resources to State, local governments, and MPOs to enable them to carry out activities that address transportation efficiency while meeting community preservation and environmental goals. Examples of such policies or programs include:

—Spending policies that direct funds to high-growth regions of the country;
—Urban growth boundaries to guide metropolitan expansion;
—''Green corridors'' programs that provide access to major highway corridors for areas targeted for efficient and compact development.

Implementation activities may include community preservation activities to implement transit-oriented development plans, traffic calming measures or other coordinated transportation and community and system preservation practices.

Priority will be given to applicants that have already instituted preservation or development programs and policies that:

1. Qualify for Federal highway and transit funding (to be determined by FHWA);

2. Coordinate with State and locally adopted preservation and development plans;

3. Integrate transportation and community and system preservation practices;

4. Promote investments in transportation infrastructure and transportation activities that minimize adverse environmental impacts and lower total life cycle costs; and/or

5. Encourage private sector investments and innovative strategies that address the purposes of TCSP.

Implementation grants will help carry out the results of planning activities that may have been funded by planning grants under this same program. In future years of the TCSP, applicants who have completed activities using planning grants will be encouraged to apply for implementation grants. We expect the results of an implementation grant to affect the way new projects are designed and constructed in the future.

Evaluation

Every proposal funded under the planning and implementation grant programs must include a description of the applicant's plans for monitoring and analysis of the grant activity and for providing the results of such monitoring and analysis to the FHWA. This information is necessary to provide an opportunity for the Department of Transportation, States, MPOs and local governments to learn more about the practical implications of integrating land development, transportation and environmental decision making.

The measures used to evaluate project results should be based on the goals and objectives of the project. In addition to individual project evaluations, an overall program evaluation will be conducted under the research component of the program described above.

Developing measures to determine the results of the projects is difficult and there is no general consensus on operative measures. The FHWA, the FTA and other Federal partners will work with grantees to develop and test measures. Methods to measure and evaluate current and future performance may include, for example:

1. Quantitative assessments such as measurement of changes in traffic flow and mode choice (e.g. increased pedestrian and bicycle traffic), environmental impacts and reduced vehicle miles of travel or number of trips;

2. Analytic procedures which forecast the current and future impacts of projects such as travel demand, land development, or economic forecasting; and/or

3. Qualitative assessment such as interviews, surveys, changes in local ordinances, or other anecdotal evidence.

Relationship of the TCSP to the Transportation Planning Process

The TCSP will complement, improve and enhance the Statewide and MPO planning process created by Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub.L. 102–240, 105 Stat.1914, and refined by TEA–21. This process promotes the ongoing, cooperative and active involvement of the public, transportation providers, public interest groups, and State, metropolitan and local government agencies in the development of statewide and metropolitan transportation plans and improvement programs (23 CFR part 450).

The DOT fully supports this planning process, which has brought diverse constituencies and government agencies together, and views the TCSP activities as a logical step in the continuing improvement of transportation planning at the State and regional level. In particular, the TCSP can help broaden the scope and impact of the planning process to better integrate land development planning, environmental goals and objectives, economic development, social equity considerations, and other private sector activities. The integration of interest groups, investors and developers through partnering with government applicants is a goal of the program. The TCSP activities will also consider incorporation of much longer planning horizons and consider the impacts on future generations.

Activities funded by this program may be used to test or implement new, innovative planning methods and programs that significantly enhance the existing Statewide and MPO transportation planning processes. The TCSP funds are intended to leverage new transportation and community preservation initiatives rather than to fund the ongoing planning activities of States and MPOs. The TCSP-funded activities must demonstrate coordination with the State and/or MPO to ensure the planning process is not circumvented. In addition, activities should encourage and improve public involvement in the overall planning process as well as in the individual project.

Construction projects funded by the TCSP will ultimately be included in an approved State or MPO Transportation Improvement Program (TIP). The TCSP funds should not be requested for projects that have already been scheduled for funding and are in the current State or MPO TIP. Highway and transit projects which either use Federal funds or require Federal approvals, and are in air quality non attainment or maintenance areas, must be included in an air quality conformity analysis required as part of the transportation planning process. Because TCSP projects may target improved air quality as part of their broader goals, documentation of the beneficial air quality impacts of the project will be important.

Non-construction activities funded by the TCSP, such as the development of regional plans and policies, project evaluations and land development code changes, may not need to appear in a Statewide or MPO TIP, but should still have the support or endorsement of the State or MPO. Non-construction activities may result in changes to existing State and MPO plans and therefore need coordination with other jurisdictions within a metropolitan region or State.

Section II: Request for Letters of Intent for FY 1999 Planning and Implementation Grants

Introduction

To lessen the burden on potential grantees in the first round of funding, the DOT is requesting that interested State, metropolitan and local governments submit Letters of Intent (LOI) to apply for either a planning or an implementation grant for FY 1999. (Proposals for research are not being solicited.) From these LOIs, the DOT will select approximately 50 applicants who will be asked to prepare a more detailed grant request for further consideration. We anticipate making final decisions on awards early in the calendar year.

Although a single activity or proposal should not be submitted for both planning and implementation grants, applicants may apply for both planning and implementation grants for different activities. Funding is limited to a maximum of $20 million in FY 1999 and competition for those funds is expected to be high. There is no predetermined balance between planning and implementation grants to be awarded in FY 1999. Grants may be spent over a period of up to two years but no commitment can be made for second or subsequent years of grant awards. Thus, phased projects must stand alone and be capable of being implemented and producing results in each phase.

Contents of LOIs

An LOI should be approximately four pages long and should follow the sample format in the attachment to this notice. Letters from partners demonstrating their commitment to the project may be attached to the LOI. The LOI should briefly describe how the activity would addresses each of the purposes of the program and the specific criteria for planning or implementation grants. Applicants should also show public involvement, non-traditional partners and private sector participation in their project.

The DOT is particularly interested in supporting projects that are ready to begin and have plans to collect and document results that can be shared with others quickly. The LOI should highlight when the proposal would be initiated and when results are expected.

Schedule and Administrative Processes

There are several options for the administration of grants under TCSP. The FHWA has established financial management systems with the State Departments of Transportation and anticipates that most TCSP grants will be channeled through this established process. However, if another process such as a cooperative agreement or grant through another eligible agency (e.g., a public transit agency) is preferred, the applicant can work with the appropriate FHWA Division Office to develop a different funding mechanism.

An applicant should send five (5) copies of the LOI to the FHWA Division Office in the State in which the project is located within 60 days from the date of this notice. The FHWA, with the multi-agency working group described under the caption ''Outreach and Cooperation'' will recommend to the Secretary the applicants who will be asked to develop full proposals. The FHWA anticipates issuing a notice requesting FY 2000 applications in March 1999. The time line for FY 1999 applications for TCSP and a proposed time line for FY 2000 follows.

Questions about the grant program should be directed to either the FHWA Division Office or FTA Regional Office in the State in which the applicant is located.

TIME LINE FOR TCSP

TCSP milestones	FY 1999 proposed	FY 2000 proposed
Issue Federal Register Notice and Request for Letters of Intent	September 15, 1998	March 1999.
Comments and Letters of Intent due	November 15, 1998	May 1999.
Select applicants to prepare grant requests	December 9, 1998	June 1999.
Grant proposals from selected Letter of Intent due	February 16, 1999	August 1999.
Grants awarded	March 15, 1999	October 1999.

Section III: Request for Comments on Program Implementation in FY 2000 and Beyond

The TCSP is a new initiative in the transportation field and may still be unfamiliar. Consequently, the DOT is seeking comments on a wide range of questions related to the administration of the program; the size, scope and nature of projects that should be supported by the program; the role of TCSP-related activities in the planning process; and the appropriate balance between research, planning and implementation activities funded as part of the initiative. The comments and suggestions received from interested parties to this notice and other outreach activities, as well as the experience gained from the first round of grant applications, will help define the program for FY 2000 and beyond. The Department is seeking comments on the following questions, as well as on other issues relating to the implementation of the TCSP.

1. *Project selection criteria:* Should there be any additional weight or priority applied to any of the criteria for FY 2000 and beyond? Should additional criteria by which the proposals will be evaluated be added?

2. *Planning:* How can we ensure that TCSP-funded activities support the existing Statewide and metropolitan planning process? How can we support innovative activities, integrate new planning techniques and refocus the planning process to ensure TCSP-related activities are addressed? What is the best way for local governments and non-traditional partners to coordinate with the State and MPO planning process?

3. *Grants:* The TCSP addresses broad issues with regional or Statewide implications. How can we ensure improvements to a single location, neighborhood street, or job center provide meaningful community preservation impacts on the larger region? How should we balance grant-making between planning and implementation grants? Should there be a cap on the size of grants? Should land acquisition and right-of-way purchases be funded?

4. *Project timeliness:* How important should the time line be for implementation of projects in our evaluation of proposed projects?

5. *Evaluation of projects:* How can project sponsors effectively evaluate the results of activities? How can the results of individual project evaluations be used to evaluate the overall impacts of TCSP?

6. *Public and private sector involvement:* How should grantees demonstrate a commitment of non-Federal resources and effective involvement of public and private partners? How can we broaden the base of program participants and encourage participation beyond the traditional transportation community?

7. *Research:* What gaps currently exist in our knowledge of transportation and community preservation practices? What experience—both good and bad—do we have with work in this field? What tools do practitioners need to achieve the integration of these issues in the transportation planning process and in project implementation?

8. *Definitions:* A number of the terms and concepts used in the TCSP pilot program may be unfamiliar to potential grant applicants. Are there established and/or helpful definitions of ''community preservation'' practices and ''system preservation'' that can be used? What examples can be given of successful community preservation and system preservation activities?

Attachment—Example Outline for FY 1999 TCSP Letters of Intent

Summary Information:
Type Of Project Request: (Planning Grant or Implementation Grant)
Project Name And Location:
Organization:
Key Contact:
Address:
Phone/Fax/E-mail:
Estimated Grant Request:

Project Description: Briefly describe the project, the geographic scale of the proposed activity (system, region, corridor, etc.), its expected results in the short and longer term (20–40 years), and the vision you have for the ultimate impact of the activity.

Purpose and Criteria: Further describe the project and its objectives. Relate how it furthers and integrates each of the following purposes of the TCSP program:

1. Improve the efficiency of the transportation system;
2. Reduce the impacts of transportation on the environment;
3. Reduce the need for costly future investments in public infrastructure;
4. Ensure efficient access to jobs, services, and centers of trade; and
5. Examine development patterns and identify strategies to encourage private sector development patterns which achieve the goals of the TCSP.

Address the other criteria which will be used to evaluate the proposal:

a. A demonstrated commitment of non-Federal resources;
b. An evaluation component;
c. An equitable distribution of grants with respect to a diversity of populations; and
d. The participation of non-traditional partners.

For Implementation Grants applicants should also provide background information on established community preservation practices within their community that:

1. Qualify for Federal highway and transit funding;
2. Coordinate with State and locally adopted preservation and development plans;
3. Integrate with transportation and community and system preservation practices;
4. Promote investments in transportation infrastructure and transportation activities that minimize adverse environmental impacts; and
5. Encourage private sector investments and innovative strategies that address the purposes of TCSP.

Coordination

Indicate how the proposal is consistent with State and metropolitan planning processes and how MPO and/or State DOT support will be demonstrated (e.g., letter, reference to report, etc).

Partners

List, and briefly describe if necessary, the agencies, organizations, and companies participating in the activities and/or on the project team. Describe plans for involvement and/or education of the broader public. You may attach to the LOI letters of support from project partners.

Resources

List all funding, both Federal and non-Federal, and in-kind resources supporting the project.

Time Frame

State the number of months or years to complete the project, including dates of major milestones, and evaluation and reporting periods.

Evaluation

Summarize the preliminary plans for evaluation of the activity, including means of monitoring, indicators and measures of performance, and plans for reporting results. Evaluation plans should address the following:

1. The accomplishment of the objectives as outlined in the project LOI, and

2. Measurement of the short-and long-term results of the project.

Submission

The LOI and 4 copies should be mailed to the FHWA Division Office in the State of the applicant. The FHWA office addresses are listed below:

Attachment—FHWA Division Offices

State	FHWA Address, Phone No.
Alabama	500 Eastern Boulevard, Suite 200, Montgomery, 36117–2018, 334–223–7377.
Alaska	Federal Building, 9th and Glacier Ave., PO Box 21648, Juneau 99802–1648, 907–586–7422.
Arizona	234 N. Central Avenue, Suite 330, Phoenix 85004, 602–379–3646.
Arkansas	Federal Office Building, Room 3128, 700 West Capitol Avenue, Little Rock 72201, 501–324–6441.
California	980 9th Street, Suite 400, Sacramento 95814–2724, 916–498–5034.
Colorado	555 Zang Street, Room 250, Lakewood 80228, 303–969–6730.
Connecticut	628–2 Hebron Avenue, Suite 303, Glastonbury 06033, 860–659–6703.
Delaware	300 South New Street, Room 2101, Dover 19904–6726, 302–734–2835.
District of Columbia	Union Center Plaza, 820 First Street, N.E., Suite 750, Washington 20002, 202–523–0163.
Florida	227 North Bronough Street, Room 2015, Tallahassee 32301, 850–942–9605.
Georgia	61 Forsyth St., SW, 17th Floor, Suite 17T100, Atlanta 30303–3104, 404–562–3634.
Hawaii	300 Ala Moana Boulevard, Suite 3202, Box 50206, Honolulu 96850, 808–541–2700.
Idaho	3050 Lakeharbor Lane, Suite 126, Boise 83703, 208–334–1843.
Illinois	3250 Executive Park Drive, Springfield 62703, 217–492–4638.
Indiana	Federal Office Building, Room 254, 575 North Pennsylvania Street, Indianapolis 46204, 317–226–7492.
Iowa	105 6th Street, PO Box 627, Ames 50010, 515–233–7315.
Kansas	3300 South Topeka Blvd., Suite 1, Topeka 66611–2237, 785–267–7284.
Kentucky	John C. Watts Building, 330 West Broadway Street, PO Box 536, Frankfort 40602, 502–223–6727.
Louisiana	750 Florida St., Room 239, PO Box 3929, Baton Rouge 70821, 504–389–0400.
Maine	Federal Building, Room 614, 40 Western Avenue, Augusta 04330, 207–622–8350.
Maryland	The Rotunda, Suite 220, 711 West 40th Street, Baltimore 21211–2187, 410–962–4342.
Massachusetts	Transportation Systems Center, 55 Broadway, 10th Floor, Cambridge 02142 617–494–2253.
Michigan	315 West Allegan Street, Room 207, Lansing 48933, 517–377–1880.
Minnesota	Galtier Plaza (Box 75) 175 5th Street E., Suite 500, St. Paul 55501–2901, 612–291–6109.
Mississippi	666 North Street, Suite 105, Jackson 39202, 601–965–4232.
Missouri	209 Adams Street, PO Box 1787, Jefferson City 65102, 573–636–7104.
Montana	301 South Park Street, Room 448, Helena 59626–0056, 406–441–1230.
Nebraska	100 Centennial Mall North, Room 220, Lincoln 68508, 402–437–5964.
Nevada	705 North Plaza Street, Suite 220, Carson City 89701, 702–687–5332.
New Hampshire	279 Pleasant Street, Room 204, Concord 03301, 603–225–1643.
New Jersey	840 Bear Tavern Road, Suite 310, West Trenton 08628–1019, 609–637–4211.
New Mexico	604 W. San Mateo Road, Santa Fe 87501, 505–820–2026.
New York	Leo W. O'Brien Federal Building, Clinton & N. Pearl Sts., 9th Floor, Albany 12207, 518–431–4125.
North Carolina	310 New Bern Avenue, Suite 410, Raleigh 27601, 919–856–4330.
North Dakota	1471 Interstate Loop, Bismarck 58501–0567, 701–250–4349.
Ohio	200 North High Street, Room 328, Columbus 43215, 614–469–5877.
Oklahoma	715 South Metropolitan, Suite 700, Oklahoma City 73108, 405–945–6040.
Oregon	Equitable Center, Suite 100, 530 Center St., N.E., Salem 97301, 503–399–5749.
Pennsylvania	Forum Place, 555 Walnut Street, Harrisburg 17101–1900, 717–221–3759.
Puerto Rico	US Courthouse & Federal Building, Carlos Chardon St., Rm 329, San Juan 00918-1755, 787–766–5600.
Rhode Island	380 Westminster Mall, Room 547, Providence 02903, 401–528–4548.
South Carolina	1835 Assembly Street, Suite 758, Columbia 29201, 803–253–3881.
South Dakota	Federal Office Building, 116 East Dakota Avenue, PO Box 700, Pierre 57501 605–224–8033.
Tennessee	249 Cumberland Bend Drive, Nashville 37228, 615–736–7106.
Texas	Federal Office Building, Room 826, 300 East Eighth Street, Austin 78701, 512–916–5917.
Utah	2520 W. 4700 South, Suite 9A, Salt Lake City 84118, 801–963–0182.
Vermont	Federal Building, 87 State St., PO Box 568, Montpelier 05601, 802–828–4433.
Virginia	Dale Building, Suite 205, 1504 Santa Rosa Road, Richmond 23229, 804–281–5111.
Washington	501 Evergreen Plaza, 711 South Capitol Way, Olympia 98501, 360–753–9485.
West Virginia	Geary Plaza, Suite 200, 700 Washington Street. E, Charleston 25301, 304–347–5329.
Wisconsin	567 D'Onofrio Drive, Madison 53719–2814, 608–829–7514.
Wyoming	1916 Evans Avenue, Cheyenne 82001–3764, 307–772–2004.

FHWA/FTA METROPOLITAN OFFICES

New York	6 World Trade Center, Room 320, New York, NY 10048, FAX: 212–466–1939 212–466–3483, 26 Federal Plaza, Suite 2940, New York, NY 10278–0194, FAX 212–264–8973, 212–264–8162.
Philadelphia	1760 Market St., Suite 510, Philadelphia, Pa 19103, 215–656–7070, FAX: 215–656-7260, 215–656–7111.
Chicago	200 West Adams, Room 2410, Chicago, IL 60606, 312–886–1616, FAX 312–886–0351, 312–886–1604.
Los Angeles	201 N. Figueroa Street, Suite 1460, Los Angeles, CA 90012; 213–202–3950; FAX: 213–202–3961.

(23 U.S.C. 315; sec. 1221, Pub. L. 105–178, 112 Stat. 107, 221 (1998); 49 CFR 1.48)

Issued on: September 11, 1998.

Kenneth R. Wykle,

Federal Highway Administration Administrator.

[FR Doc. 98–24850 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Applications for Modification of Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for modification of exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modifications of exemptions (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix ''M'' denote a modification request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before October 1, 1998.

ADDRESS COMMENTS TO: Records Center, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, Nassif Building, 400 7th Street SW, Washington, DC.

Application No.	Docket No.	Applicant	Modification of exemption
10672–M	.....	Burlington Packaging, Inc. Brooklyn, NY (See Footnote 1)	10672
11173–M	.....	Olin Corporation (See Footnote 2)	11173
12062–M	RSPA–1998–3790.	Wood Protection Products, Inc. Charlotte, NC (See Footnote 3)	12062
12107–M	RSPA–1998–4065.	Toyota Motor Sales, U.S.A., Inc. Torrance, CA (See Footnote 4)	12107
12112–M	RSPA–1998–4322.	HRD Aero Systems, Inc. Valencia, CA (See Footnote 5)	12112

(*1*) To modify the exemption to provide for passenger air as an additional mode of transportation for shipping liquid and solid hazardous materials required to bear the POISON, KEEP AWAY FROM FOOD, FLAMMABLE LIQUID, FLAMMABLE SOLID OR CORROSIVE labels in specially-designed composite type packaging.

(*2*) To modify the exemption to authorize the use of DOT specification 110A multi-unit tanks for the transportation by cargo aircraft of certain Division 6.1 and Class 8 materials which exceed the quantity limitations.

(*3*) To authorize party status and to authorize a similarly designed non-DOT specification, pneumatic hopper trailer for the transportation of a 6.1 material.

(*4*) To reissue the exemption originally issued on an emergency basis for the manufacture, mark and sale of certain shock absorbers, struts, stays and dampers for transportation in commerce as accumulators.

(*5*) To reissue the exemption originally issued on an emergency basis for the transportation in commerce of certain 2.2 gases in non-DOT specification copper cylinders used as components (fire extinguishers) in aircraft of foreign manufacturers.

This notice of receipt of applications for modification of exemptions is published in accordance with Part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on September 10, 1998.

J. Suzanne Hedgepeth,

Director, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 98–24757 Filed 9–15–98; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Applications for Exemptions

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applicants for exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follow: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before October 16, 1998.

ADDRESS COMMENTS TO: Records Center, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION CONTACT:

Copies of the applications (See Docket Number) are available for inspection at the New Docket Management Facility, PL–401, at the U.S. Department of Transportation, Nassif Building, 400 7th Street, SW., Washington, DC 20590.

This notice of receipt of applications for new exemptions is published in accordance with Part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806, 49 CFR 1.53(e)).

Issued in Washington, DC, on September 10, 1998.

J. Suzanne Hedgepeth,

Director, Office of Hazardous Materials, Exemptions and Approvals.

NEW EXEMPTIONS

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of exemption thereof
12128–N	RPSA–1998–4392	Ogden Waste Solutions, Inc., Okahumpka, FL.	49 CFR 171.8, 172.101 Column (8C), 173.197.	To authorize the transportation in commerce of non-DOT specification steel roll-off containers as outer packagings for transportation in commerce of regulated medical waste in dual packagings. (mode 1).
12129–N	RPSA–1998–4387	Kenyon International Emergency Services Houston, TX.	49 CFR 175.75(a)(1)(2) ..	To authorize the transportation in commerce of small quantities of various hazardous materials that exceed the specified quantity limitation. (mode 5).
12130–N	RPSA–1998–4386	FIBA Technologies, Inc., Westboro, MA.	49 CFR 173.318, 176.30, 176.76(h), 178.338.	To authorize the manufacture, marking and sale of non-DOT specification insulated portable tanks for the transportation in commerce of carbon dioxide, refrigerated liquid. (modes 1, 3).
12131–N	RPSA–1998–4385	Gamma Laboratories, Ltd., Houston, TX.	49 CFR 173.302, 173.306(b)(4), 175.3.	To authorize the manufacture, mark and sale of non-DOT specification packagings, used as radiation detectors, for shipments of certain non-flammable compressed gases. (modes 1, 2, 3, 4, 5).
12132–N	RPSA–1998–4415	Carleton Technologies, Inc., Orchard, NY.	49 CFR 178.65	To authorize the transportation in commerce of a specially designed device consisting of a hermetically sealed high pressure gas cylinder, containing argon gas, Division 1.4S. (modes 1, 2, 3, 4).
12133–N	RPSA–1998–4416	Polar Air Cargo, Washington, DC.	49 CFR 172.101(9B), 172.204(a) & (c), 173.27, 173.54(j), 175.30(a)(1).	To authorize the transportation in commerce of certain Division 1.1, 1.2, 1.3, and 1.4 explosives which are forbidden or exceed quantities authorized. (mode 4).
12134–N	RPSA–1998–4417	Institute of Shortening and Edible Oils (ISEO), Washington, DC.	49 CFR Parts 100–180 ...	To authorize the transportation in commerce of sift-proof dump or hopper-type vehicles and sift-proof roll-on/roll-off bulk bins with tarpaulins, metal covers or equivalent covers for use in transporting Division 4.2 material. (mode 1).
12135–N	RPSA–1998–4418	Daicel Safety Systems, Inc.	49 CFR 173.301(h), 173.302, 173.306(d)(3).	To authorize the manufacture, mark and sale of non-DOT specification cylinders (pressure vessels) for use as components of automobile vehicle safety systems. (modes 1, 2, 3, 4).
12136–N	RPSA–1998–4419	Net Grocer, North Brunswick, NJ.	49 CFR 123, 172, Subpart C.	To authorize the transportation in commerce of small quantities of ORM–D consumer aersols without required shipping papers. (mode 4).
12138–N	RPSA–1998–4420	Gas Supply Resources, Inc. Albany, NY.	49 CFR 174.67(i) & (j)	To authorize rail cars with unloading pipes equipped with a closure device to remain attached to railcar dome unloading valves on railcars positioned at unloading towers. (moded 2).

[FR Doc. 98–24758 Filed 9–15–98; 8:45 am]

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Federal Register

Wednesday
September 16, 1998

Part II

The President

Executive Order 13101—Greening the Government Through Waste Prevention, Recycling, and Federal Acquisition

Federal Register
Vol. 63, No. 179
Wednesday, September 16, 1998

Presidential Documents

Title 3—

The President

Executive Order 13101 of September 14, 1998

Greening the Government Through Waste Prevention, Recycling, and Federal Acquisition

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Solid Waste Disposal Act, Public Law 89–272, 79 Stat. 997, as amended by the Resource Conservation and Recovery Act (RCRA), Public Law 94–580, 90 Stat. 2795, as amended (42 U.S.C. 6901–6907), section 301 of title 3, United States Code, and in order to improve the Federal Government's use of recycled products and environmentally preferable products and services, it is hereby ordered as follows:

PART 1—PREAMBLE

Section 101. Consistent with the demands of efficiency and cost effectiveness, the head of each executive agency shall incorporate waste prevention and recycling in the agency's daily operations and work to increase and expand markets for recovered materials through greater Federal Government preference and demand for such products. It is the national policy to prefer pollution prevention, whenever feasible. Pollution that cannot be prevented should be recycled; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner. Disposal should be employed only as a last resort.

Sec. 102. Consistent with policies established by the Office of Federal Procurement Policy (OFPP) Policy Letter 92–4, agencies shall comply with executive branch policies for the acquisition and use of environmentally preferable products and services and implement cost-effective procurement preference programs favoring the purchase of these products and services.

Sec. 103. This order creates a Steering Committee, a Federal Environmental Executive (FEE), and a Task Force, and establishes Agency Environmental Executive (AEE) positions within each agency, to be responsible for ensuring the implementation of this order. The FEE, AEEs, and members of the Steering Committee and Task Force shall be full-time Federal Government employees.

PART 2—DEFINITIONS

For purposes of this order:

Sec. 201. ''Environmentally preferable'' means products or services that have a lesser or reduced effect on human health and the environment when compared with competing products or services that serve the same purpose. This comparison may consider raw materials acquisition, production, manufacturing, packaging, distribution, reuse, operation, maintenance, or disposal of the product or service.

Sec. 202. ''Executive agency'' or ''agency'' means an executive agency as defined in 5 U.S.C. 105. For the purpose of this order, military departments, as defined in 5 U.S.C. 102, are covered under the auspices of the Department of Defense.

Sec. 203. ''Postconsumer material'' means a material or finished product that has served its intended use and has been discarded for disposal or recovery, having completed its life as a consumer item. ''Postconsumer material'' is a part of the broader category of ''recovered material.''

Sec. 204. ''Acquisition'' means the acquiring by contract with appropriated funds for supplies or services (including construction) by and for the use of the Federal Government through purchase or lease, whether the supplies or services are already in existence or must be created, developed, demonstrated, and evaluated. Acquisition begins at the point when agency needs are established and includes the description of requirements to satisfy agency needs, solicitation and selection of sources, award of contracts, contract financing, contract performance, contract administration, and those technical and management functions directly related to the process of fulfilling agency needs by contract.

Sec. 205. ''Recovered materials'' means waste materials and by-products that have been recovered or diverted from solid waste, but such term does not include those materials and by-products generated from, and commonly reused within, an original manufacturing process (42 U.S.C. 6903 (19)).

Sec. 206. ''Recyclability'' means the ability of a product or material to be recovered from, or otherwise diverted from, the solid waste stream for the purpose of recycling.

Sec. 207. ''Recycling'' means the series of activities, including collection, separation, and processing, by which products or other materials are recovered from the solid waste stream for use in the form of raw materials in the manufacture of new products other than fuel for producing heat or power by combustion.

Sec. 208. ''Waste prevention'' means any change in the design, manufacturing, purchase, or use of materials or products (including packaging) to reduce their amount or toxicity before they are discarded. Waste prevention also refers to the reuse of products or materials.

Sec. 209. ''Waste reduction'' means preventing or decreasing the amount of waste being generated through waste prevention, recycling, or purchasing recycled and environmentally preferable products.

Sec. 210. ''Life cycle cost'' means the amortized annual cost of a product, including capital costs, installation costs, operating costs, maintenance costs, and disposal costs discounted over the lifetime of the product.

Sec. 211. ''Life cycle assessment'' means the comprehensive examination of a product's environmental and economic aspects and potential impacts throughout its lifetime, including raw material extraction, transportation, manufacturing, use, and disposal.

Sec. 212. ''Pollution prevention'' means ''source reduction'' as defined in the Pollution Prevention Act of 1990 (42 U.S.C. 13102), and other practices that reduce or eliminate the creation of pollutants through: (a) increased efficiency in the use of raw materials, energy, water, or other resources; or (b) protection of natural resources by conservation.

Sec. 213. ''Biobased product'' means a commercial or industrial product (other than food or feed) that utilizes biological products or renewable domestic agricultural (plant, animal, and marine) or forestry materials.

Sec. 214. ''Major procuring agencies'' shall include any executive agency that procures over $50 million per year of goods and services.

PART 3—THE ROLES AND DUTIES OF THE STEERING COMMITTEE, FEDERAL ENVIRONMENTAL EXECUTIVE, TASK FORCE, AND AGENCY ENVIRONMENTAL EXECUTIVES

Sec. 301. Committees, Executives, and Task Force. (a) Steering Committee. There is hereby established a Steering Committee on Greening the Government through Waste Prevention and Recycling (''Steering Committee''). The Steering Committee shall be composed of the Chair of the Council on Environmental Quality (CEQ), the Federal Environmental Executive (FEE), and the Administrator for Federal Procurement Policy (OFPP). The Steering Committee, which shall be chaired by the Chair of the CEQ, is directed to charter a Task Force to facilitate implementation of this order, and shall provide the Task Force with policy direction in such implementation.

(b) Federal Environmental Executive. A Federal Environmental Executive, Environmental Protection Agency, shall be designated by the President. The FEE shall chair the Task Force described in subsection (c), take all actions necessary to ensure that the agencies comply with the requirements of this order, and generate a biennial report to the President.

(c) Task Force. The Steering Committee shall charter a Task Force on Greening the Government through Waste Prevention and Recycling (''Task Force''), which shall be chaired by the FEE and composed of staff from the major procuring agencies. The Steering Committee, in consultation with the agencies, shall determine the necessary staffing and resources for the Task Force. The major procuring agencies shall provide, to the extent practicable and permitted by law, resources and support to the Task Force and the FEE, upon request from the Steering Committee. The Task Force shall have the duty of assisting the FEE and the agencies in implementing this order, subject to policy direction provided by the Steering Committee. The Task Force shall report through the FEE to the Chair of the Steering Committee.

(d) Agency Environmental Executives (AEEs). Within 90 days after the date of this order, the head of each major procuring agency shall designate an AEE from among his or her staff, who serves at a level no lower than the Assistant Secretary level or equivalent, and shall notify the Chair of CEQ and the FEE of such designation.

Sec. 302. Duties. (a) The Federal Environmental Executive. The FEE, working through the Task Force, and in consultation with the AEEs, shall:

(1) Develop a Government-wide Waste Prevention and Recycling Strategic Plan (''Strategic Plan'') to further implement this order. The Strategic Plan should be initially developed within 180 days of the date of this order and revised as necessary thereafter. The Strategic Plan should include, but is not limited to, the following elements:

(a) direction and initiatives for acquisition of recycled and recyclable products and environmentally preferable products and services;

(b) development of affirmative procurement programs;

(c) review and revision of standards and product specifications;

(d) assessment and evaluation of compliance;

(e) reporting requirements;

(f) outreach programs to promote adoption of practices endorsed in this order; and

(g) development and implementation of new technologies that are of environmental significance.

(2) Prepare a biennial report to the President on the actions taken by the agencies to comply with this order. The report also may incorporate information from existing agency reports regarding Government-wide progress in implementing the following Executive Orders: 12843, Procurement Requirements and Policies for Federal Agencies for Ozone Depleting Substances; 13031, Federal Alternative Fueled Vehicle Leadership; 12845, Requiring Agencies to Purchase Energy Efficient Computer Equipment; 12856, Federal Compliance with Right-to-Know Laws and Pollution Prevention Requirements; 12902, Energy Efficiency and Water Conservation at Federal Facilities; and 12969, Federal Acquisition and Community Right-to-Know.

(3) In coordination with the Office of Federal Procurement Policy, the Environmental Protection Agency (EPA), the General Services Administration (GSA), and the Department of Agriculture (USDA), convene a group of acquisition/procurement managers and environmental State, and local government managers to work with State and local governments to improve the Federal, State, and local governments' use of recycled products and environmentally preferable products and services.

(4) Coordinate appropriate Government-wide education and training programs for agencies.

(5) Establish committees and work groups, as needed, to identify, assess, and recommend actions to be taken to fulfill the goals, responsibilities, and initiatives of the FEE. As these committees and work groups are created, agencies are requested to designate appropriate personnel in the areas of procurement and acquisition, standards and specifications, electronic commerce, facilities management, pollution prevention, waste prevention, recycling, and others as needed to staff and work on these initiatives. An initial group shall be established to develop recommendations for tracking and reporting requirements, taking into account the costs and benefits of such tracking and reporting. The Steering Committee shall consult with the AEEs before approving these recommendations.

(b) Agency Environmental Executives. The AEEs shall:

(1) translate the Government-wide Strategic Plan into specific agency and service plans;

(2) implement the specific agency and service plans;

(3) report to the FEE on the progress of plan implementation;

(4) work with the FEE and the Task Force in furthering implementation of this order; and

(5) track agencies' purchases of EPA-designated guideline items and report agencies' purchases of such guideline items to the FEE per the recommendations developed in subsection 302(a)(5) of this order. Agency acquisition and procurement personnel shall justify in writing to the file and to the AEE the rationale for not purchasing such items, above the micropurchase threshold (as set out in the Office of Federal Procurement Policy Act at 41 U.S.C. 428), and submit a plan and timetable for increasing agency purchases of the designated item(s).

(6) one year after a product is placed on the USDA Biobased Products List, estimate agencies' purchases of products on the list and report agencies' estimated purchases of such products to the Secretary of Agriculture.

PART 4—ACQUISITION PLANNING, AFFIRMATIVE PROCUREMENT PROGRAMS, AND FEDERAL FACILITY COMPLIANCE

Sec. 401. Acquisition Planning. In developing plans, drawings, work statements, specifications, or other product descriptions, agencies shall consider, as appropriate, a broad range of factors including: elimination of virgin material requirements; use of biobased products; use of recovered materials; reuse of product; life cycle cost; recyclability; use of environmentally preferable products; waste prevention (including toxicity reduction or elimination); and ultimate disposal. These factors should be considered in acquisition planning for all procurement and in the evaluation and award of contracts, as appropriate. Program and acquisition managers should take an active role in these activities.

Sec. 402. Affirmative Procurement Programs. (a) The head of each executive agency shall develop and implement affirmative procurement programs in accordance with section 6002 of RCRA (42 U.S.C. 6962) and this order and consider use of the procurement tools and methods described in 7 U.S.C. 5909. Agencies shall ensure that responsibilities for preparation, implementation, and monitoring of affirmative procurement programs are shared between the program personnel and acquisition and procurement personnel. For the purposes of all purchases made pursuant to this order, EPA, in consultation with such other executive agencies as appropriate, shall endeavor to maximize environmental benefits, consistent with price, performance, and availability considerations, and constraints imposed by law, and shall adjust solicitation guidelines as necessary in order to accomplish this goal.

(b) Agencies shall establish affirmative procurement programs for all EPA-designated guideline items purchased by their agency. For newly designated items, agencies shall revise their internal programs within 1 year from the date the EPA designated the new items.

(c) Exclusive of the biobased products described in section 504, for the EPA-designated guideline items, which are contained in 40 CFR part 247, and for all future designated guideline items, agencies shall ensure that their affirmative procurement programs require 100 percent of their purchases of products to meet or exceed the EPA guideline unless written justification is provided that a product is not available competitively within a reasonable time frame, does not meet appropriate performance standards, or is only available at an unreasonable price. Written justification is not required for purchases below the micropurchase threshold. For micropurchases, agencies shall provide guidance regarding purchase of EPA-designated guideline items. This guidance should encourage consideration of aggregating purchases when this method would promote economy and efficiency.

(d) Within 90 days after the date of this order, the head of each executive agency that has not implemented an affirmative procurement program shall ensure that the affirmative procurement program has been established and is being implemented to the maximum extent practicable.

Sec. 403. Federal Facility Compliance. (a) Within 6 months of the date of this order, the Administrator of the EPA shall, in consultation with the Federal Environmental Executive, prepare guidance for use in determining Federal facility compliance with section 6002 of RCRA and the related requirements of this order.

(b) EPA inspections of Federal facilities conducted pursuant to RCRA and the Federal Facility Compliance Act and EPA ''multi-media'' inspections carried out at Federal facilities will include, where appropriate, evaluation of facility compliance with section 6002 of RCRA and any implementing guidance.

(c) Where inspections of Federal facilities are carried out by authorized States pursuant to RCRA and the Federal Facility Compliance Act, the Administrator of the EPA will encourage those States to include evaluation of facility compliance with section 6002 of RCRA in light of EPA guidance prepared pursuant to subsection (a), where appropriate, similar to inspections performed by the EPA. The EPA may provide information and technical assistance to the States to enable them to include such considerations in their inspection.

(d) The EPA shall report annually to the Federal Environmental Executive on the results of inspections performed by the EPA to determine Federal facility compliance with section 6002 of RCRA not later than February 1st for those inspections conducted during the previous fiscal year.

PART 5—STANDARDS, SPECIFICATIONS, AND DESIGNATION OF ITEMS

Sec. 501. Specifications, Product Descriptions, and Standards. When developing, reviewing, or revising Federal and military specifications, product descriptions (including commercial item descriptions), and standards, executive agencies shall consider recovered materials and any environmentally preferable purchasing criteria developed by the EPA, and ensure the criteria are complied with in developing or revising standards. Agencies shall report annually to the FEE on their compliance with this section for incorporation into the biennial report to the President referred to in section 302(a)(2) of this order. (a) If an inconsistency with section 6002 of RCRA or this order is identified in a specification, standard, or product description, the FEE shall request that the Environmental Executive of the pertinent agency advise the FEE as to why the specification cannot be revised or submit a plan for revising it within 60 days.

(b) If an agency is able to revise an inconsistent specification but cannot do so within 60 days, it is the responsibility of that AEE to monitor and implement the plan for revising it.

Sec. 502. Designation of Items that Contain Recovered Materials. In order to expedite the process of designating items that are or can be made with recovered materials, the EPA shall use the following process for designating these items in accordance with section 6002(e) of RCRA. (a) The EPA shall designate items that are or can be made with recovered material, by promul-

gating amendments to the Comprehensive Procurement Guideline (CPG). The CPG shall be updated every 2 years or as appropriate after an opportunity for public comment.

(b) Concurrent with the issuance of the CPG, the EPA shall publish for comment in the **Federal Register** Recovered Materials Advisory Notices that present the range of recovered materials content levels within which the designated items are currently available. These levels shall be updated periodically, after opportunity for public comment, to reflect changes in market conditions.

(c) Once items containing recovered materials have been designated by the EPA in the CPG, agencies shall modify their affirmative procurement programs to require that, to the maximum extent practicable, their purchases of products meet or exceed the EPA guidelines unless written justification is provided that a product is not available competitively, not available within a reasonable time frame, does not meet appropriate performance standards, or is only available at an unreasonable price.

Sec. 503. Guidance on Acquisition of Environmentally Preferable Products and Services. (a) The EPA shall develop guidance within 90 days from the date of this order to address environmentally preferable purchasing. The guidance may be based on the EPA's September 1995 Proposed Guidance on the Acquisition of Environmentally Preferable Products and Services and comments received thereon. The guidance should be designed for Government-wide use and targeted towards products and services that have the most effect. The guidance may also address the issues of use of the technical expertise of nongovernmental entities and tools such as life cycle assessment in decisions on environmentally preferable purchasing. The EPA shall update this guidance every 2 years, or as appropriate.

(b) Agencies are encouraged to immediately test and evaluate the principles and concepts contained in the EPA's Guidance on the Acquisition of Environmentally Preferable Products and Services through pilot projects to provide practical information to the EPA for further updating of the guidance. Specifically:

(1) These pilot projects shall be focused around those product and service categories, including printing, that have wide use within the Federal Government. Priorities regarding which product and service categories to pilot shall be developed by the individual agencies and the EPA, in consultation with the OFPP, the FEE, and the appropriate agency procurement executives. Any policy disagreements shall be resolved by the Steering Committee.

(2) Agencies are encouraged to use all of the options available to them to determine the environmentally preferable attributes of products and services in their pilot and demonstration projects, including the use of technical expertise of nongovernmental entities such as labeling, certification, or standards-developing organizations, as well as using the expertise of the National Institute of Standards and Technology.

(3) Upon request and to the extent practicable, the EPA shall assist executive agencies in designing, implementing, and documenting the results of these pilot and demonstration projects.

(4) The EPA, in coordination with other executive agencies, shall develop a database of information about these projects, including, but not limited to, the number and status of pilot projects, examples of agencies' policy directives, revisions to specifications, solicitation procedures, and grant/contract policies that facilitate adoption of environmentally preferable purchasing practices, to be integrated on a commonly available electronic medium (e.g., Internet Web site). These data are to be reported to the FEE.

(c) Executive agencies shall use the principles and concepts in the EPA Guidance on Acquisition of Environmentally Preferable Products and Services, in addition to the lessons from the pilot and demonstration projects, to the maximum extent practicable, in identifying and purchasing environ-

mentally preferable products and services and shall modify their procurement programs as appropriate.

Sec. 504. Designation of Biobased Items by the USDA. The USDA Biobased Products Coordination Council shall, in consultation with the FEE, issue a Biobased Products List. (a) The Biobased Products List shall be published in the **Federal Register** by the USDA within 180 days after the date of this order and shall be updated biannually after publication to include additional items.

(b) Once the Biobased Products List has been published, agencies are encouraged to modify their affirmative procurement program to give consideration to those products.

Sec. 505. Minimum Content Standard for Printing and Writing Paper. Executive agency heads shall ensure that their agencies meet or exceed the following minimum materials content standards when purchasing or causing the purchase of printing and writing paper: (a) For high speed copier paper, offset paper, forms bond, computer printout paper, carbonless paper, file folders, white wove envelopes, writing and office paper, book paper, cotton fiber paper, and cover stock, the minimum content standard shall be no less than 30 percent postconsumer materials beginning December 31, 1998. If paper containing 30 percent postconsumer material is not reasonably available, does not meet reasonable performance requirements, or is only available at an unreasonable price, then the agency shall purchase paper containing no less than 20 percent postconsumer material. The Steering Committee, in consultation with the AEEs, may revise these levels if necessary.

(b) As an alternative to meeting the standards in sections 505(a), for all printing and writing papers, the minimum content standard shall be no less than 50 percent recovered materials that are a waste material byproduct of a finished product other than a paper or textile product that would otherwise be disposed of in a landfill, as determined by the State in which the facility is located.

(c) Effective January 1, 1999, no executive branch agency shall purchase, sell, or arrange for the purchase of, printing and writing paper that fails to meet the minimum requirements of this section.

Sec. 506. Revision of Brightness Specifications and Standards. The GSA and other executive agencies are directed to identify, evaluate, and revise or eliminate any standards or specifications unrelated to performance that present barriers to the purchase of paper or paper products made by production processes that minimize emissions of harmful byproducts. This evaluation shall include a review of unnecessary brightness and stock clause provisions, such as lignin content and chemical pulp requirements. The GSA shall complete the review and revision of such specifications within 6 months after the date of this order, and shall consult closely with the Joint Committee on Printing during such process. The GSA shall also compile any information or market studies that may be necessary to accomplish the objectives of this provision.

Sec. 507. Procurement of Re-refined Lubricating Oil and Retread Tires. (a) Agencies shall implement the EPA procurement guidelines for re-refined lubricating oil and retread tires. Fleet and commodity managers shall take immediate steps, as appropriate, to procure these items in accordance with section 6002 of RCRA. This provision does not preclude the acquisition of biobased (e.g., vegetable) oils.

(b) The FEE shall work to educate executive agencies about the new Department of Defense Cooperative Tire Qualification Program, including the Cooperative Approval Tire List and Cooperative Plant Qualification Program, as they apply to retread tires.

PART 6—AGENCY GOALS AND REPORTING REQUIREMENTS

Sec. 601. Agency Goals. (a)(1) Each agency shall establish either a goal for solid waste prevention and a goal for recycling or a goal for solid waste diversion to be achieved by January 1, 2000. Each agency shall further

ensure that the established goals include long-range goals to be achieved by the years 2005 and 2010. These goals shall be submitted to the FEE within 180 days after the date of this order. (2) In addition to white paper, mixed paper/cardboard, aluminum, plastic, and glass, agencies should incorporate into their recycling programs efforts to recycle, reuse, or refurbish pallets and collect toner cartridges for remanufacturing. Agencies should also include programs to reduce or recycle, as appropriate, batteries, scrap metal, and fluorescent lamps and ballasts.

(b) Agencies shall set goals to increase the procurement of products that are made with recovered materials, in order to maximize the number of recycled products purchased, relative to non-recycled alternatives.

(c) Each agency shall set a goal for increasing the use of environmentally preferable products and services for those products and services for which the agency has completed a pilot program.

(d) Agencies are encouraged to incorporate into their Government Performance Results Act annual performance plans the goals listed in subsections (a), (b), and (c) above, starting with the submittal to the Office of Management and Budget of the plan accompanying the FY 2001 budget.

(e) Progress on attaining these goals should be reported by the agencies to the FEE for the biennial report specified in section 302(a)(2) of this order.

PART 7—APPLICABILITY AND OTHER REQUIREMENTS

Sec. 701. Contractor Applicability. Contracts that provide for contractor operation of a Government-owned or -leased facility and/or contracts that provide for contractor or other support services at Government-owned or -operated facilities awarded by executive agencies after the date of this order, shall include provisions that obligate the contractor to comply with the requirements of this order within the scope of its operations.

Sec. 702. Real Property Acquisition and Management. Within 90 days after the date of this order, and to the extent permitted by law and where economically feasible, executive agencies shall ensure compliance with the provisions of this order in the acquisition and management of Federally owned and leased space. The GSA and other executive agencies shall also include environmental and recycling provisions in the acquisition and management of all leased space and in the construction of new Federal buildings.

Sec. 703. Retention of Funds. (a) The Administrator of General Services shall continue with the program that retains for the agencies the proceeds from the sale of materials recovered through recycling or waste prevention programs and specifying the eligibility requirements for the materials being recycled.

(b) Agencies in non-GSA managed facilities, to the extent permitted by law, should develop a plan to retain the proceeds from the sale of materials recovered through recycling or waste prevention programs.

Sec. 704. Model Facility Programs. Each executive agency shall establish a model demonstration program incorporating some or all of the following elements as appropriate. Agencies are encouraged to demonstrate and test new and innovative approaches such as incorporating environmentally preferable and bio-based products; increasing the quantity and types of products containing recovered materials; expanding collection programs; implementing source reduction programs; composting organic materials when feasible; and exploring public/private partnerships to develop markets for recovered materials.

Sec. 705. Recycling Programs. (a)(1) Each executive agency that has not already done so shall initiate a program to promote cost-effective waste prevention and recycling of reusable materials in all of its facilities. The recycling programs implemented pursuant to this section must be compatible with applicable State and local recycling requirements.

(2) Agencies shall designate a recycling coordinator for each facility or installation. The recycling coordinator shall implement or maintain waste prevention and recycling programs in the agencies' action plans.

(b) Executive agencies shall also consider cooperative ventures with State and local governments to promote recycling and waste reduction in the community.

Sec. 706. Review of Implementation. The President's Council on Integrity and Efficiency shall request that the Inspectors General periodically review agencies' implementation of this order.

PART 8—AWARENESS

Sec. 801. Training. (a) Within 180 days of the date of this order, the FEE and OFPP should evaluate the training courses provided by the Federal Acquisition Institute and the Defense Acquisition University and recommend any appropriate curriculum changes to ensure that procurement officials are aware of the requirements of this order.

(b) Executive agencies shall provide training to program management and requesting activities as needed to ensure awareness of the requirements of this order.

Sec. 802. Internal Agency Awards Programs. Each agency shall develop an internal agency-wide awards program, as appropriate, to reward its most innovative environmental programs. Among others, winners of agency-wide awards will be eligible for the White House Awards Program.

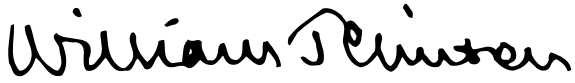
Sec. 803. White House Awards Program. A Government-wide award will be presented annually by the White House to the best, most innovative programs implementing the objectives of this order to give greater visibility to these efforts so that they can be incorporated Government-wide. The White House Awards Program will be administered jointly by the FEE and the CEQ.

PART 9—REVOCATION, LIMITATION, AND IMPLEMENTATION

Sec. 901. Executive Order 12873 of October 20, 1993, is hereby revoked.

Sec. 902. This order is intended only to improve the internal management of the executive branch and is not intended to create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other person.

Sec. 903. The policies and direction expressed in the EPA guidance to be developed pursuant to section 503 of this order shall be implemented and incorporated in the Federal Acquisition Regulation within 180 days after issuance of the guidance.



THE WHITE HOUSE,
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